

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 411, 414, 423, and 425

[CMS-1600-FC]

RIN 0938-AR56

Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2014.

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule with comment period.

SUMMARY: This major final rule with comment period addresses changes to the physician fee schedule, clinical laboratory fee schedule, and other Medicare Part B payment policies to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services. This final rule with comment period also includes a discussion in the Supplementary Information regarding various programs. (See the Table of Contents for a listing of the specific issues addressed in the final rule with comment period.)

DATES: Effective date: The provisions of this final rule with comment period are effective on January 1, 2014, except for the amendments to §\$405.350, 405.355, 405.405.2413, 405.2415, 405.2452, 410.19, 410.26, 410.37, 410.71, 410.74, 410.75, 410.76, 410.77, and 414.511, which are effective January 27, 2014, and the amendments to §\$405.201, \$405.203, \$405.205, \$405.207, \$405.209, \$405.211, \$405.212, \$405.213, \$411.15, and 423.160, which are effective on January 1, 2015.

The incorporation by reference of certain publications listed in the rule is approved by the Director of the **Federal Register** as of January 1, 2014.

<u>Applicability dates</u>: Additionally, the policies specified in under the following preamble sections are applicable January 27, 2014:

- Physician Compare Website (section III.G.);
- Physician Self-Referral Prohibition: Annual Update to the List of CPT/HCPCS Codes.
 (section III.N.)

<u>Comment date</u>: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on January 27, 2014. (See the SUPLEMENTARY INFORMATION section of this final rule with comment period for a list of the provisions open for comment.)

ADDRESSES: In commenting, please refer to file code CMS-1600-FC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

- 1. <u>Electronically</u>. You may submit electronic comments on this regulation to www.regulations.gov. Follow the instructions for "submitting a comment."
 - 2. By regular mail. You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services.

Department of Health and Human Services,

Attention: CMS-1600-FC,

P.O. Box 8013,

Baltimore, MD 21244-8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-1600-FC,

Mail Stop C4-26-05,

7500 Security Boulevard,

Baltimore, MD 21244-1850.

4. <u>By hand or courier</u>. If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC--

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Room 445-G, Hubert H. Humphrey Building,

200 Independence Avenue, SW.,

Washington, DC 20201

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stampin clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD--

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

7500 Security Boulevard,

Baltimore, MD 21244-1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786-7195 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

FOR FURTHER INFORMATION CONTACT:

Elliott Isaac, (410) 786–4735 or Elliott.Isaac@cms.hhs.gov, for any physician payment issues not identified below.

Chava Sheffield, (410) 786–2298 or Chava.Sheffield@cms.hhs.gov, for issues related to practice expense methodology, impacts, the sustainable growth rate, or conversion factors.

Ryan Howe, (410) 786–3355 or Ryan.Howe@cms.hhs.gov, for issues related to direct practice expense inputs or interim final direct PE inputs.

Kathy Kersell, (410) 786–2033 or Kathleen.Kersell@cms.hhs.gov, for issues related to misvalued services.

Jessica Bruton, (410) 786-5991 or Jessica.Bruton@cms.hhs.gov, for issues related to work or malpractice RVUs.

Heidi Oumarou, (410) 786–7942 or Heidi.Oumarou@cms.hhs.gov, for issues related to the revision of Medicare Economic Index (MEI).

Gail Addis, (410) 786-4552 or Gail.Addis@cms.hhs.gov, for issues related to the refinement panel.

Craig Dobyski, (410) 786–4584 or Craig.Dobyski@cms.hhs.gov, for issues related to geographic practice cost indices.

Ken Marsalek, (410) 786–4502 or Kenneth.Marsalek@cms.hhs.gov, for issues related to telehealth services.

Simone Dennis, (410) 786–8409 or Simone.Dennis@cms.hhs.gov, for issues related to therapy caps.

Darlene Fleischmann, (410) 786–2357 or Darlene.Fleischmann@cms.hhs.gov, for issues related to "incident to" services or complex chronic care management services.

Corinne Axelrod, (410) 786–5620 or Corrine.Axelrod@cms.hhs.gov, for issues related to "incident to" services in Rural Health Clinics or Federally Qualified Health Centers.

Roberta Epps, (410) 786–4503 or Roberta. Epps@cms.hhs.gov, for issues related to chiropractors billing for evaluation and management services.

Rosemarie Hakim, (410) 786–3934 or Rosemarie.Hakim@cms.hhs.gov, for issues related to coverage of items and services furnished in FDA-approved investigational device exemption clinical trials.

Jamie Hermansen, (410) 786–2064 or Jamie.Hermansen@cms.hhs.gov or Jyme Schafer, (410) 786–4643 or Jyme.Schafer@cms.hhs.gov, for issues related to ultrasound screening for abdominal aortic aneurysms or colorectal cancer screening.

Anne Tayloe-Hauswald, (410) 786–4546 or Anne-E-Tayloe.Hauswald@cms.hhs.gov, for issues related to ambulance fee schedule and clinical lab fee schedule.

Ronke Fabayo, (410) 786–4460 or Ronke.Fabayo@cms.hhs.gov or Jay Blake, (410) 786–9371 or Jay.Blake@cms.hhs.gov, for issues related to individual liability for payments made to providers and suppliers and handling of incorrect payments.

Rashaan Byers, (410) 786–2305 or Rashaan.Byers@cms.hhs.gov, for issues related to physician compare.

Christine Estella, (410) 786–0485 or Christine. Estella@cms.hhs.gov, for issues related to the physician quality reporting system and EHR incentive program.

Sandra Adams, (410) 786–8084 or Sandra.Adams@cms.hhs.gov, for issues related to Medicare Shared Savings Program.

Michael Wrobleswki, (410) 786–4465 or Michael.Wrobleswki@cms.hhs.gov, for issues related to value-based modifier and improvements to physician feedback.

Andrew Morgan, (410) 786–2543 or Andrew.Morgan@cms.hhs.gov, for issues related to e-prescribing under Medicare Part D.

Pauline Lapin, (410)786–6883 or Pauline.Lapin@cms.hhs.gov, for issues related to the chiropractic services demonstration budget neutrality issue.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: http://www.regulations.gov. Follow the search instructions on that website to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

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Acronyms

In addition, because of the many organizations and terms to which we refer by acronym in this final rule with comment period, we are listing these acronyms and their corresponding terms in alphabetical order below:

AAA Abdominal aortic aneurysms

ACA Affordable Care Act (Pub. L. 111–148)

ACO Accountable care organization

AHE Average hourly earnings

AMA American Medical Association

AMA RUC AMA [Specialty Society] Relative (Value) Update Committee

ASC Ambulatory surgical center

ATRA American Taxpayer Relief Act (Pub. L. 112-240)

AWV Annual wellness visit

BBA Balanced Budget Act of 1997 (Pub. L. 105-33)

BBRA [Medicare, Medicaid and State Child Health Insurance Program] Balanced Budget

Refinement Act of 1999 (Pub. L. 106-113)

BEA Bureau of Economic Analysis

CAH Critical access hospital

CBSA Core-Based Statistical Area

CCM Chronic Care Management

CED Coverage with evidence development

CEHRT Certified EHR technology

CF Conversion factor

CLFS Clinical Laboratory Fee Schedule

CMD Contractor medical director

CMHC Community mental health center

CMT Chiropractic manipulative treatment

CORF Comprehensive outpatient rehabilitation facility

CPC Comprehensive Primary Care

CPEP Clinical Practice Expert Panel

CPI-U Consumer Price Index for Urban Areas

CPS Current Population Survey

CPT [Physicians] Current Procedural Terminology (CPT codes, descriptions and other

data only are copyright 2013 American Medical Association. All rights reserved.)

CQM Clinical quality measure

CT Computed tomography

CTA Computed tomographic angiography

CY Calendar year

DFAR Defense Federal Acquisition Regulations

DHS Designated health services

DRA Deficit Reduction Act of 2005 (Pub. L.109–171)

DSMT Diabetes self-management training

ECEC Employer Costs for Employee Compensation

ECI Employment Cost Index

eCQM Electronic clinical quality measures

EHR Electronic health record

EMTALA Emergency Medical Treatment and Labor Act

eRx Electronic prescribing

ESRD End-stage renal disease

FAR Federal Acquisition Regulations

FFS Fee-for-service

FOBT Fecal occult blood test

FQHC Federally qualified health center

FR Federal Register

GAF Geographic adjustment factor

GAO Government Accountability Office

GPCI Geographic practice cost index

GPRO Group practice reporting option

HCPCS Healthcare Common Procedure Coding System

HHS [Department of] Health and Human Services

HOPD Hospital outpatient department

HPSA Health professional shortage area

IDE Investigational device exemption

IDTF Independent diagnostic testing facility

IOM Institute of Medicine

IPPE Initial Preventive Physical Examination

IPPS Inpatient Prospective Payment System

IQR Inpatient Quality Reporting

IWPUT Intensity of work per unit of time

KDE Kidney disease education

LCD Local coverage determination

LDT Laboratory-developed test

MA Medicare Advantage

MAC Medicare Administrative Contractor

MAPCP Multi-payer Advanced Primary Care Practice

MCTRJCA Middle Class Tax Relief and Job Creation Act of 2012 (Pub. L. 112-96)

MDC Major diagnostic category

MedPAC Medicare Payment Advisory Commission

MEI Medicare Economic Index

MFP Multi-Factor Productivity

MGMA Medical Group Management Association

MIEA-TRHCA The Medicare Improvements and Extension Act, Division B of the Tax

Relief and Health Care Act (Pub. L. 109-432)

MIPPA Medicare Improvements for Patients and Providers Act (Pub. L. 110-275)

MMEA Medicare and Medicaid Extenders Act (Pub. L. 111-309)

MMSEA Medicare, Medicaid, and State Children's Health Insurance Program Extension

Act (Pub. L. 110-73)

MP Malpractice

MPPR Multiple procedure payment reduction

MRA Magnetic resonance angiography

MRI Magnetic resonance imaging

MSA Metropolitan Statistical Areas

MSPB Medicare Spending per Beneficiary

MSSP Medicare Shared Savings Program

MU Meaningful use

NCD National coverage determination

NCQDIS National Coalition of Quality Diagnostic Imaging Services

NP Nurse practitioner

NPI National Provider Identifier

NPP Nonphysician practitioner

OACT CMS's Office of the Actuary

OBRA '89 Omnibus Budget Reconciliation Act of 1989

OBRA '90 Omnibus Budget Reconciliation Act of 1990

OES Occupational Employment Statistics

OMB Office of Management and Budget

OPPS Outpatient prospective payment system

PC Professional component

PCIP Primary Care Incentive Payment

PDP Prescription Drug Plan

PE Practice expense

PE/HR Practice expense per hour

PEAC Practice Expense Advisory Committee

PECOS Provider Enrollment, Chain, and Ownership System

PFS Physician Fee Schedule

PLI Professional Liability Insurance

PMA Premarket approval

POS Place of Service

PQRS Physician Quality Reporting System

PPIS Physician Practice Expense Information Survey

QRUR Quality and Resources Use Report

RBRVS Resource-based relative value scale

RFA Regulatory Flexibility Act

RHC Rural health clinic

RIA Regulatory impact analysis

RoPR Registry of Patient Registries

RUCA Rural Urban Commuting Area

RVU Relative value unit

SBA Small Business Administration

SGR Sustainable growth rate

SMS Socioeconomic Monitoring System

SNF Skilled nursing facility

SOI Statistics of Income

TAP Technical Advisory Panel

TC Technical component

TIN Tax identification number

TPTCCA Temporary Payroll Tax Cut Continuation Act (Pub. L. 112-78)

UAF Update adjustment factor

USPSTF United States Preventive Services Task Force

VBP Value-based purchasing

VBM Value-Based Modifier

Addenda Available Only Through the Internet on the CMS Website

The PFS Addenda along with other supporting documents and tables referenced in this final rule with comment period are available through the Internet on the CMS website at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html. Click on the link on the left side of the screen titled, "PFS Federal Regulations Notices" for a chronological list of PFS Federal Register and other related documents. For the CY 2014 PFS final rule with comment period, refer to item CMS-1600-FC. Readers who experience any problems accessing any of the Addenda or other documents referenced in this final rule with comment period and posted on the CMS website identified above should contact Elliot.Isaac@cms.hhs.gov.

CPT (Current Procedural Terminology) Copyright Notice

Throughout this final rule with comment period, we use CPT codes and descriptions to refer to a variety of services. We note that CPT codes and descriptions are copyright 2013

American Medical Association. All Rights Reserved. CPT is a registered trademark of the American Medical Association (AMA). Applicable Federal Acquisition Regulations (FAR) and Defense Federal Acquisition Regulations (DFAR) apply.

I. Executive Summary and Background

A. Executive Summary

1. Purpose

This major final rule with comment period revises payment polices under the Medicare Physician Fee Schedule (PFS) and makes other policy changes related to Medicare Part B payment. Unless otherwise noted, these changes are applicable to services furnished in CY 2014.

2. Summary of the Major Provisions

The Social Security Act (Act) requires us to establish payments under the PFS based on national uniform relative value units (RVUs) that account for the relative resources used in furnishing a service. The Act requires that RVUs be established for three categories of resources: work, practice expense (PE); and malpractice (MP) expense; and that we establish by regulation each year payment amounts for all physicians' services, incorporating geographic adjustments to reflect the variations in the costs of furnishing services in different geographic areas. In this major final rule with comment period, we establish RVUs for CY 2014 for the PFS, and other Medicare Part B payment policies, to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services as well as changes in the statute. In addition, this final rule with comment period includes discussions and/or policy changes regarding:

- Misvalued PFS Codes.
- Telehealth Services.
- Applying Therapy Caps to Outpatient Therapy Services Furnished by CAHs.
- Requiring Compliance with State law as a Condition of Payment for Services Furnished Incident to Physicians' (and Other Practitioners') Services.
 - Revising the MEI based on MEI TAP Recommendations.
 - Updating the Ambulance Fee Schedule regulations.

• Adjusting the Clinical Laboratory Fee Schedule based on technological changes

- Updating the-
 - ++ Physician Compare Website.
 - ++ Physician Quality Reporting System.
 - ++ Electronic Prescribing (eRx) Incentive Program.
 - ++ Medicare Shared Savings Program.
 - ++ Electronic Health Record (EHR) Incentive Program.
- Budget Neutrality for the Chiropractic Services Demonstration.
- Physician Value-Based Payment Modifier and the Physician Feedback Reporting Program.

3. Summary of Costs and Benefits

We have determined that this final rule with comment period is economically significant. For a detailed discussion of the economic impacts, see section VII. of this final rule with comment period.

B. Background

Since January 1, 1992, Medicare has paid for physicians' services under section 1848 of the Act, "Payment for Physicians' Services." The system relies on national relative values that are established for work, PE, and MP, which are then adjusted for geographic cost variations. These values are multiplied by a conversion factor (CF) to convert the RVUs into payment rates. The concepts and methodology underlying the PFS were enacted as part of the Omnibus Budget Reconciliation Act of 1989 (OBRA '89) (Pub. L. 101-239, enacted on December 19, 1989), and the Omnibus Budget Reconciliation Act of 1990 (OBRA '90 (Pub. L. 101-508, enacted on

November 5, 1990). The final rule published on November 25, 1991 (56 FR 59502) set forth the first fee schedule used for payment for physicians' services.

We note that throughout this final rule with comment period, unless otherwise noted, the term "practitioner" is used to describe both physicians and nonphysician practitioners who are permitted to bill Medicare under the PFS for services furnished to Medicare beneficiaries.

1. Development of the Relative Values

a. Work RVUs

The physician work RVUs established for the implementation of the fee schedule in January 1992 were developed with extensive input from the physician community. A research team at the Harvard School of Public Health developed the original physician work RVUs for most codes under a cooperative agreement with the Department of Health and Human Services (HHS). In constructing the code-specific vignettes used in determining the original physician work RVUs, Harvard worked with panels of experts, both inside and outside the federal government, and obtained input from numerous physician specialty groups.

We establish work RVUs for new and revised codes based, in part, on our review of recommendations received from the American Medical Association/Specialty Society Relative Value Update Committee (AMA RUC).

b. Practice Expense RVUs

Initially, only the work RVUs were resource-based, and the PE and MP RVUs were based on average allowable charges. Section 121 of the Social Security Act Amendments of 1994 (Pub. L. 103-432, enacted on October 31, 1994), amended section 1848(c)(2)(C)(ii) of the Act and required us to develop resource-based PE RVUs for each physicians' service beginning in 1998. We were required to consider general categories of expenses (such as office

rent and wages of personnel, but excluding malpractice expenses) comprising PEs. Originally, this method was to be used beginning in 1998, but section 4505(a) of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105-33, enacted on August 5, 1997) delayed implementation of the resource-based PE RVU system until January 1, 1999. In addition, section 4505(b) of the BBA provided for a 4-year transition period from the charge-based PE RVUs to the resource-based PE RVUs.

We established the resource-based PE RVUs for each physicians' service in a final rule, published November 2, 1998 (63 FR 58814), effective for services furnished in CY 1999. Based on the requirement to transition to a resource-based system for PE over a 4-year period, payment rates were not fully based upon resource-based PE RVUs until CY 2002. This resource-based system was based on two significant sources of actual PE data: the Clinical Practice Expert Panel (CPEP) data and the AMA's Socioeconomic Monitoring System (SMS) data. (These data sources are described in greater detail in the CY 2012 final rule with comment period (76 FR 73033).)

Separate PE RVUs are established for services furnished in facility settings, such as a hospital outpatient department (HOPD) or an ambulatory surgical center (ASC), and in non-facility settings, such as a physician's office. The nonfacility RVUs reflect all of the direct and indirect PEs involved in furnishing a service described by a particular HCPCS code. The difference, if any, in these PE RVUs generally results in a higher payment in the nonfacility setting because in the facility settings some costs are borne by the facility. Medicare's payment to the facility (such as the outpatient prospective payment system (OPPS) payment to the HOPD) would reflect costs typically incurred by the facility. Thus, payment associated with those facility resources is not made under the PFS.

Section 212 of the Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106-113, enacted on November 29, 1999) directed the Secretary of Health and Human Services (the Secretary) to establish a process under which we accept and use, to the maximum extent practicable and consistent with sound data practices, data collected or developed by entities and organizations to supplement the data we normally collect in determining the PE component. On May 3, 2000, we published the interim final rule (65 FR 25664) that set forth the criteria for the submission of these supplemental PE survey data. The criteria were modified in response to comments received, and published in the **Federal Register** (65 FR 65376) as part of a November 1, 2000 final rule. The PFS final rules published in 2001 and 2003, respectively, (66 FR 55246 and 68 FR 63196) extended the period during which we would accept these supplemental data through March 1, 2005.

In the CY 2007 PFS final rule with comment period (71 FR 69624), we revised the methodology for calculating direct PE RVUs from the top-down to the bottom-up methodology beginning in CY 2007. We adopted a 4-year transition to the new PE RVUs. This transition was completed for CY 2010. In the CY 2010 PFS final rule with comment period, we updated the practice expense per hour (PE/HR) data that are used in the calculation of PE RVUs for most specialties (74 FR 61749). In CY 2010, we began a 4-year transition to the new PE RVUs using the updated PE/HR data, which was completed for CY 2013.

c. Malpractice RVUs

Section 4505(f) of the BBA amended section 1848(c) of the Act to require that we implement resource-based MP RVUs for services furnished on or after CY 2000. The resource-based MP RVUs were implemented in the PFS final rule with comment period published November 2, 1999 (64 FR 59380). The MP RVUs are based on malpractice insurance

premium data collected from commercial and physician-owned insurers from all the states, the District of Columbia, and Puerto Rico.

d. Refinements to the RVUs

Section 1848(c)(2)(B)(i) of the Act requires that we review RVUs no less often than every 5 years. Prior to CY 2013, we conducted periodic reviews of work RVUs and PE RVUs independently. We completed Five-Year Reviews of Work RVUs that were effective for calendar years 1997, 2002, 2007, and 2012.

While refinements to the direct PE inputs initially relied heavily on input from the AMA RUC Practice Expense Advisory Committee (PEAC), the shifts to the bottom-up PE methodology in CY 2007 and to the use of the updated PE/HR data in CY 2010 have resulted in significant refinements to the PE RVUs in recent years.

In the CY 2012 PFS final rule with comment period (76 FR 73057), we finalized a proposal to consolidate reviews of work and PE RVUs under section 1848(c)(2)(B) of the Act and reviews of potentially misvalued codes under section 1848(c)(2)(K) of the Act into one annual process.

With regard to MP RVUs, we completed Five-Year Reviews of MP that were effective in CY 2005 and CY 2010.

In addition to the Five-Year Reviews, beginning for CY 2009, CMS and the AMA RUC have identified and reviewed a number of potentially misvalued codes on an annual basis based on various identification screens. This annual review of work and PE RVUs for potentially misvalued codes was supplemented by the amendments to section 1848 of the Act, as enacted by section 3134 of the Affordable Care Act, which requires the agency to periodically identify,

review and adjust values for potentially misvalued codes with an emphasis on seven specific categories (see section II.C.2. of this final rule with comment period).

e. Application of Budget Neutrality to Adjustments of RVUs

As described in section VII.C.1. of this final rule with comment period, in accordance with section 1848(c)(2)(B)(ii)(II) of the Act, if revisions to the RVUs would cause expenditures for the year to change by more than \$20 million, we make adjustments to ensure that expenditures do not increase or decrease by more than \$20 million.

2. Calculation of Payments Based on RVUs

To calculate the payment for each physicians' service, the components of the fee schedule (work, PE, and MP RVUs) are adjusted by geographic practice cost indices (GPCIs) to reflect the variations in the costs of furnishing the services. The GPCIs reflect the relative costs of physician work, PE, and MP in an area compared to the national average costs for each component. (See section II.F.2 of this final rule with comment period for more information about GPCIs.)

RVUs are converted to dollar amounts through the application of a CF, which is calculated based on a statutory formula by CMS's Office of the Actuary (OACT). The CF for a given year is calculated using (a) the productivity-adjusted increase in the Medicare Economic Index (MEI) and (b) the Update Adjustment Factor (UAF), which is calculated by taking into account the Medicare Sustainable Growth Rate (SGR), an annual growth rate intended to control growth in aggregate Medicare expenditures for physicians' services, and the allowed and actual expenditures for physicians' services. For a more detailed discussion of the calculation of the CF, the SGR, and the MEI, we refer readers to section II.G. of this final rule with comment period.

The formula for calculating the Medicare fee schedule payment amount for a given service and fee schedule area can be expressed as:

Payment = [(RVU work x GPCI work) + (RVU PE x GPCI PE) + (RVU MP x GPCI MP)] x CF.

3. Separate Fee Schedule Methodology for Anesthesia Services

Section 1848(b)(2)(B) of the Act specifies that the fee schedule amounts for anesthesia services are to be based on a uniform relative value guide, with appropriate adjustment of an anesthesia conversion factor, in a manner to assure that fee schedule amounts for anesthesia services are consistent with those for other services of comparable value. Therefore, there is a separate fee schedule methodology for anesthesia services. Specifically, we establish a separate conversion factor for anesthesia services and we utilize the uniform relative value guide, or base units, as well as time units, to calculate the fee schedule amounts for anesthesia services. Since anesthesia services are not valued using RVUs, a separate methodology for locality adjustments is also necessary. This involves an adjustment to the national anesthesia CF for each payment locality.

4. Most Recent Changes to the Fee Schedule

The CY 2013 PFS final rule with comment period (77 FR 68892) implemented changes to the PFS and other Medicare Part B payment policies. It also finalized many of the CY 2012 interim final RVUs and established interim final RVUs for new and revised codes for CY 2013 to ensure that our payment system is updated to reflect changes in medical practice, coding changes, and the relative values of services. It also implemented certain statutory provisions including provisions of the Affordable Care Act (Pub. L. 111–148) and the Middle Class Tax

Relief and Jobs Creation Act (MCTRJCA) (Pub. L. 112-96), including claims-based data reporting requirements for therapy services.

In the CY 2013 PFS final rule with comment period, we announced the following for CY 2013: the total PFS update of -26.5 percent; the initial estimate for the SGR of -19.7 percent; and the CY 2013 CF of \$25.0008. These figures were calculated based on the statutory provisions in effect on November 1, 2012, when the CY 2013 PFS final rule with comment period was issued.

On January 2, 2013, the American Taxpayer Relief Act (ATRA) of 2012 (Pub. L. 112-240) was signed into law. Section 601(a) of the ATRA specified a zero percent update to the PFS CF for CY 2013. As a result, the CY 2013 PFS conversion factor was revised to \$34.0320. In addition, the ATRA extended and added several provisions affecting Medicare services furnished in CY 2013, including:

- Section 602 extending the 1.0 floor on the work geographic practice cost index through CY 2013;
- Section 603 extending the exceptions process for outpatient therapy caps through CY 2013, extending the application of the cap and manual medical review threshold to services furnished in the HOPD through CY 2013, and requiring the counting of a proxy amount for therapy services furnished in a Critical Access Hospital (CAH) toward the cap and threshold during CY 2013.

In addition to the changes effective for CY 2013, section 635 of ATRA revised the equipment utilization rate assumption for advanced imaging services furnished on or after January 1, 2014.

A correction document (78 FR 48996) was issued to correct several technical and typographical errors that occurred in the CY 2013 PFS final rule with comment period.

II. Provisions of the Final Rule with Comment Period for PFS

A. Resource-Based Practice Expense (PE) Relative Value Units (RVUs)

1. Overview

Practice expense (PE) is the portion of the resources used in furnishing a service that reflects the general categories of physician and practitioner expenses, such as office rent and personnel wages, but excluding malpractice expenses, as specified in section 1848(c)(1)(B) of the Act. Section 121 of the Social Security Amendments of 1994 (Pub. L. 103-432), enacted on October 31, 1994, amended section 1848(c)(2)(C)(ii) of the Act to require us to develop a methodology for a resource-based system for determining PE RVUs for each physician's service. We develop PE RVUs by looking at the direct and indirect practice resources involved in furnishing each service. Direct expense categories include clinical labor, medical supplies, and medical equipment. Indirect expenses include administrative labor, office expense, and all other expenses. The sections that follow provide more detailed information about the methodology for translating the resources involved in furnishing each service into service-specific PE RVUs. We refer readers to the CY 2010 PFS final rule with comment period (74 FR 61743 through 61748) for a more detailed explanation of the PE methodology.

In addition, we note that section 1848(c)(2)(B)(ii)(II) of the Act provides that adjustments in RVUs for a year may not cause total PFS payments to differ by more than \$20 million from what they would have otherwise been if the adjustments were not made. Therefore, if revisions to the RVUs cause expenditures to change by more than \$20 million, we make adjustments to ensure that expenditures do not increase or decrease by more than \$20 million.

2. Practice Expense Methodology

a. Direct Practice Expense

We determine the direct PE for a specific service by adding the costs of the direct resources (that is, the clinical staff, equipment, and supplies) typically involved with furnishing that service. The costs of the resources are calculated using the refined direct PE inputs assigned to each CPT code in our PE database, which are based on our review of recommendations received from the AMA RUC and those provided in response to public comment periods. For a detailed explanation of the direct PE methodology, including examples, we refer readers to the Five-Year Review of Work Relative Value Units Under the PFS and Proposed Changes to the Practice Expense Methodology proposed notice (71 FR 37242) and the CY 2007 PFS final rule with comment period (71 FR 69629).

b. Indirect Practice Expense per Hour Data

We use survey data on indirect PEs incurred per hour worked in developing the indirect portion of the PE RVUs. Prior to CY 2010, we primarily used the practice expense per hour (PE/HR) by specialty that was obtained from the AMA's Socioeconomic Monitoring Surveys (SMS). The AMA administered a new survey in CY 2007 and CY 2008, the Physician Practice Expense Information Survey (PPIS). The PPIS is a multispecialty, nationally representative, PE survey of both physicians and nonphysician practitioners (NPPs) paid under the PFS using a survey instrument and methods highly consistent with those used for the SMS and the supplemental surveys. The PPIS gathered information from 3,656 respondents across 51 physician specialty and health care professional groups. We believe the PPIS is the most comprehensive source of PE survey information available. We used the PPIS data to update the PE/HR data for the CY 2010 PFS for almost all of the Medicare-recognized specialties that

participated in the survey.

When we began using the PPIS data in CY 2010, we did not change the PE RVU methodology itself or the manner in which the PE/HR data are used in that methodology. We only updated the PE/HR data based on the new survey. Furthermore, as we explained in the CY 2010 PFS final rule with comment period (74 FR 61751), because of the magnitude of payment reductions for some specialties resulting from the use of the PPIS data, we transitioned its use over a 4-year period (75 percent old/25 percent new for CY 2010, 50 percent old/50 percent new for CY 2011, 25 percent old/75 percent new for CY 2012, and 100 percent new for CY 2013) from the previous PE RVUs to the PE RVUs developed using the new PPIS data. As provided in the CY 2010 PFS final rule with comment period (74 FR 61751), the transition to the PPIS data was complete for CY 2013. Therefore, the CY 2013 and CY 2014 PE RVUs are developed based entirely on the PPIS data, except as noted in this section.

Section 1848(c)(2)(H)(i) of the Act requires us to use the medical oncology supplemental survey data submitted in 2003 for oncology drug administration services.

Therefore, the PE/HR for medical oncology, hematology, and hematology/oncology reflects the continued use of these supplemental survey data.

Supplemental survey data on independent labs from the College of American Pathologists were implemented for payments beginning in CY 2005. Supplemental survey data from the National Coalition of Quality Diagnostic Imaging Services (NCQDIS), representing independent diagnostic testing facilities (IDTFs), were blended with supplementary survey data from the American College of Radiology (ACR) and implemented for payments beginning in CY 2007. Neither IDTFs, nor independent labs, participated in the PPIS. Therefore, we continue to use the PE/HR that was developed from their supplemental survey data.

Consistent with our past practice, the previous indirect PE/HR values from the supplemental surveys for these specialties were updated to CY 2006 using the MEI to put them on a comparable basis with the PPIS data.

We also do not use the PPIS data for reproductive endocrinology and spine surgery since these specialties currently are not separately recognized by Medicare, nor do we have a method to blend the PPIS data with Medicare-recognized specialty data.

We do not use the PPIS data for sleep medicine since there is not a full year of Medicare utilization data for that specialty given the specialty code was only available beginning in October 1, 2012. We anticipate using the PPIS data to create PE/HR for sleep medicine for CY 2015 when we will have a full year of data to make the calculations.

Previously, we established PE/HR values for various specialties without SMS or supplemental survey data by crosswalking them to other similar specialties to estimate a proxy PE/HR. For specialties that were part of the PPIS for which we previously used a crosswalked PE/HR, we instead used the PPIS-based PE/HR. We continue previous crosswalks for specialties that did not participate in the PPIS. However, beginning in CY 2010 we changed the PE/HR crosswalk for portable x-ray suppliers from radiology to IDTF, a more appropriate crosswalk because these specialties are more similar to each other with respect to physician time.

For registered dietician services, the resource-based PE RVUs have been calculated in accordance with the final policy that crosswalks the specialty to the "All Physicians" PE/HR data, as adopted in the CY 2010 PFS final rule with comment period (74 FR 61752) and discussed in more detail in the CY 2011 PFS final rule with comment period (75 FR 73183).

c. Allocation of PE to Services

To establish PE RVUs for specific services, it is necessary to establish the direct

and indirect PE associated with each service.

(1) Direct Costs

The relative relationship between the direct cost portions of the PE RVUs for any two services is determined by the relative relationship between the sum of the direct cost resources (that is, the clinical staff, equipment, and supplies) typically involved with furnishing each of the services. The costs of these resources are calculated from the refined direct PE inputs in our PE database. For example, if one service has a direct cost sum of \$400 from our PE database and another service has a direct cost sum of \$200, the direct portion of the PE RVUs of the first service would be twice as much as the direct portion of the PE RVUs for the second service.

(2) Indirect Costs

Section II.B.2.b. of this final rule with comment period describes the current data sources for specialty-specific indirect costs used in our PE calculations. We allocated the indirect costs to the code level on the basis of the direct costs specifically associated with a code and the greater of either the clinical labor costs or the physician work RVUs. We also incorporated the survey data described earlier in the PE/HR discussion. The general approach to developing the indirect portion of the PE RVUs is described as follows:

• For a given service, we use the direct portion of the PE RVUs calculated as previously described and the average percentage that direct costs represent of total costs (based on survey data) across the specialties that furnish the service to determine an initial indirect allocator. In other words, the initial indirect allocator is calculated so that the direct costs equal the average percentage of direct costs of those specialties furnishing the service. For example, if the direct portion of the PE RVUs for a given service is 2.00

and direct costs, on average, represented 25 percent of total costs for the specialties that furnished the service, the initial indirect allocator would be calculated so that it equals 75 percent of the total PE RVUs. Thus, in this example the initial indirect allocator would equal 6.00, resulting in a total PE RVUs of 8.00 (2.00 is 25 percent of 8.00 and 6.00 is 75 percent of 8.00).

- Next, we add the greater of the work RVUs or clinical labor portion of the direct portion of the PE RVUs to this initial indirect allocator. In our example, if this service had work RVUs of 4.00 and the clinical labor portion of the direct PE RVUs was 1.50, we would add 4.00 (since the 4.00 work RVUs are greater than the 1.50 clinical labor portion) to the initial indirect allocator of 6.00 to get an indirect allocator of 10.00. In the absence of any further use of the survey data, the relative relationship between the indirect cost portions of the PE RVUs for any two services would be determined by the relative relationship between these indirect cost allocators. For example, if one service had an indirect cost allocator of 10.00 and another service had an indirect cost allocator of 5.00, the indirect portion of the PE RVUs of the first service would be twice as great as the indirect portion of the PE RVUs for the second service.
- Next, we incorporate the specialty-specific indirect PE/HR data into the calculation. In our example, if based on the survey data, the average indirect cost of the specialties furnishing the first service with an allocator of 10.00 was half of the average indirect cost of the specialties furnishing the second service with an indirect allocator of 5.00, the indirect portion of the PE RVUs of the first service would be equal to that of the second service.
- d. Facility and Nonfacility Costs

For procedures that can be furnished in a physician's office, as well as in a hospital or facility setting, we establish two PE RVUs: facility and nonfacility. The methodology for calculating PE RVUs is the same for both the facility and nonfacility RVUs, but is applied independently to yield two separate PE RVUs. Because in calculating the PE RVUs for services furnished in a facility, we do not include resources that would generally not be provided by physicians when furnishing the service in a facility, the facility PE RVUs are generally lower than the nonfacility PE RVUs. Medicare makes a separate payment to the facility for its costs of furnishing a service.

e. Services with Technical Components (TCs) and Professional Components (PCs)

Diagnostic services are generally comprised of two components: a professional component (PC); and a technical component (TC). The PC and TC may be furnished independently or by different providers, or they may be furnished together as a "global" service. When services have separately billable PC and TC components, the payment for the global service equals the sum of the payment for the TC and PC. To achieve this we use a weighted average of the ratio of indirect to direct costs across all the specialties that furnish the global service, TCs, and PCs; that is, we apply the same weighted average indirect percentage factor to allocate indirect expenses to the global service, PCs, and TCs for a service. (The direct PE RVUs for the TC and PC sum to the global under the bottom-up methodology.)

f. PE RVU Methodology

For a more detailed description of the PE RVU methodology, we refer readers to the CY 2010 PFS final rule with comment period (74 FR 61745 through 61746).

(1) Setup File

First, we create a setup file for the PE methodology. The setup file contains the direct cost inputs, the utilization for each procedure code at the specialty and facility/nonfacility place of service level, and the specialty-specific PE/HR data calculated from the surveys.

(2) Calculate the Direct Cost PE RVUs

Sum the costs of each direct input.

Step 1: Sum the direct costs of the inputs for each service. Apply a scaling adjustment to the direct inputs.

Step 2: Calculate the aggregate pool of direct PE costs for the current year. This is the product of the current aggregate PE (direct and indirect) RVUs, the CF, and the average direct PE percentage from the survey data used for calculating the PE/HR by specialty.

Step 3: Calculate the aggregate pool of direct PE costs for use in ratesetting. This is the product of the aggregated direct costs for all services from Step 1 and the utilization data for that service. For CY 2014, we adjusted the aggregate pool of direct PE costs in proportion to the change in the PE share in the revised MEI, as discussed in section II.D. of this final rule with comment period.

Step 4: Using the results of Step 2 and Step 3, calculate a direct PE scaling adjustment to ensure that the aggregate pool of direct PE costs calculated in Step 3 does not vary from the aggregate pool of direct PE costs for the current year. Apply the scaling factor to the direct costs for each service (as calculated in Step 1).

Step 5: Convert the results of Step 4 to an RVU scale for each service. To do this, divide the results of Step 4 by the CF. Note that the actual value of the CF used in

this calculation does not influence the final direct cost PE RVUs, as long as the same CF is used in Step 2 and Step 5. Different CFs will result in different direct PE scaling factors, but this has no effect on the final direct cost PE RVUs since changes in the CFs and changes in the associated direct scaling factors offset one another.

(3) Create the Indirect Cost PE RVUs

Create indirect allocators.

<u>Step 6</u>: Based on the survey data, calculate direct and indirect PE percentages for each physician specialty.

Step 7: Calculate direct and indirect PE percentages at the service level by taking a weighted average of the results of Step 6 for the specialties that furnish the service.

Note that for services with TCs and PCs, the direct and indirect percentages for a given service do not vary by the PC, TC, and global service.

Step 8: Calculate the service level allocators for the indirect PEs based on the percentages calculated in Step 7. The indirect PEs are allocated based on the three components: the direct PE RVUs; the clinical PE RVUs; and the work RVUs.

For most services the indirect allocator is: indirect PE percentage * (direct PE RVUs/direct percentage) + work RVUs.

There are two situations where this formula is modified:

- If the service is a global service (that is, a service with global, professional, and technical components), then the indirect PE allocator is: indirect percentage (direct PE RVUs/direct percentage) + clinical PE RVUs + work RVUs.
- If the clinical labor PE RVUs exceed the work RVUs (and the service is not a global service), then the indirect allocator is: indirect PE percentage (direct

PE RVUs/direct percentage) + clinical PE RVUs.

(Note: For global services, the indirect PE allocator is based on both the work RVUs and the clinical labor PE RVUs. We do this to recognize that, for the PC service, indirect PEs will be allocated using the work RVUs, and for the TC service, indirect PEs will be allocated using the direct PE RVUs and the clinical labor PE RVUs. This also allows the global component RVUs to equal the sum of the PC and TC RVUs.)

For presentation purposes in the examples in Table 1, the formulas were divided into two parts for each service.

- The first part does not vary by service and is the indirect percentage (direct PE RVUs/direct percentage).
- The second part is either the work RVU, clinical labor PE RVU, or both depending on whether the service is a global service and whether the clinical PE RVUs exceed the work RVUs (as described earlier in this step).

Apply a scaling adjustment to the indirect allocators.

Step 9: Calculate the current aggregate pool of indirect PE RVUs by multiplying the current aggregate pool of PE RVUs by the average indirect PE percentage from the survey data.

Step 10: Calculate an aggregate pool of indirect PE RVUs for all PFS services by adding the product of the indirect PE allocators for a service from Step 8 and the utilization data for that service. For CY 2014, we adjusted the indirect cost pool in proportion to the change in the PE share in the revised MEI, as discussed in section II.D. of this final rule with comment period.

Step 11: Using the results of Step 9 and Step 10, calculate an indirect PE

adjustment so that the aggregate indirect allocation does not exceed the available aggregate indirect PE RVUs and apply it to indirect allocators calculated in Step 8.

Calculate the indirect practice cost index.

Step 12: Using the results of Step 11, calculate aggregate pools of specialty-specific adjusted indirect PE allocators for all PFS services for a specialty by adding the product of the adjusted indirect PE allocator for each service and the utilization data for that service.

Step 13: Using the specialty-specific indirect PE/HR data, calculate specialty-specific aggregate pools of indirect PE for all PFS services for that specialty by adding the product of the indirect PE/HR for the specialty, the physician time for the service, and the specialty's utilization for the service across all services furnished by the specialty.

Step 14: Using the results of Step 12 and Step 13, calculate the specialty-specific indirect PE scaling factors.

Step 15: Using the results of Step 14, calculate an indirect practice cost index at the specialty level by dividing each specialty-specific indirect scaling factor by the average indirect scaling factor for the entire PFS.

Step 16: Calculate the indirect practice cost index at the service level to ensure the capture of all indirect costs. Calculate a weighted average of the practice cost index values for the specialties that furnish the service. (Note: For services with TCs and PCs, we calculate the indirect practice cost index across the global service, PCs, and TCs. Under this method, the indirect practice cost index for a given service (for example, echocardiogram) does not vary by the PC, TC, and global service.)

Step 17: Apply the service level indirect practice cost index calculated in Step 16 to the service level adjusted indirect allocators calculated in Step 11 to get the indirect PE RVUs.

(4) Calculate the Final PE RVUs

Step 18: Add the direct PE RVUs from Step 6 to the indirect PE RVUs from Step 17 and apply the final PE budget neutrality (BN) adjustment and the MEI revision adjustment.

The final PE BN adjustment is calculated by comparing the results of Step 18 to the current pool of PE RVUs (prior to the adjustments corresponding with the MEI revision described in section II.D. of this final rule with comment period). This final BN adjustment is required to redistribute RVUs from step 18 to all PE RVUs in the PFS, and because certain specialties are excluded from the PE RVU calculation for ratesetting purposes, but we note that all specialties are included for purposes of calculating the final BN adjustment. (See "Specialties excluded from ratesetting calculation" later in this section.)

(5) Setup File Information

• Specialties excluded from ratesetting calculation: For the purposes of calculating the PE RVUs, we exclude certain specialties, such as certain nonphysician practitioners paid at a percentage of the PFS and low-volume specialties, from the calculation. These specialties are included for the purposes of calculating the BN adjustment. They are displayed in Table 1.

TABLE 1: Specialties Excluded From Ratesetting Calculation

Specialty	Specialty Description
Code	
49	Ambulatory surgical center
50	Nurse practitioner
51	Medical supply company with certified orthotist
52	Medical supply company with certified prosthetist
53	Medical supply company with certified prosthetist-orthotist
54	Medical supply company not included in 51, 52, or 53.
55	Individual certified orthotist
56	Individual certified prosthestist
57	Individual certified prosthetist-orthotist
58	Individuals not included in 55, 56, or 57
59	Ambulance service supplier, e.g., private ambulance companies, funeral homes, etc.
60	Public health or welfare agencies
61	Voluntary health or charitable agencies
73	Mass immunization roster biller
74	Radiation therapy centers
87	All other suppliers (e.g., drug and department stores)
88	Unknown supplier/provider specialty
89	Certified clinical nurse specialist
95	Competitive Acquisition Program (CAP) Vendor
96	Optician
97	Physician assistant
A0	Hospital
A1	SNF
A2	Intermediate care nursing facility
A3	Nursing facility, other
A4	ННА
A5	Pharmacy
A6	Medical supply company with respiratory therapist
A7	Department store
1	Supplier of oxygen and/or oxygen related equipment
2	Pedorthic personnel
3	Medical supply company with pedorthic personnel

- <u>Crosswalk certain low volume physician specialties</u>: Crosswalk the utilization of certain specialties with relatively low PFS utilization to the associated specialties.
 - Physical therapy utilization: Crosswalk the utilization associated with all

physical therapy services to the specialty of physical therapy.

• Identify professional and technical services not identified under the usual TC and 26 modifiers: Flag the services that are PC and TC services, but do not use TC and 26 modifiers (for example, electrocardiograms). This flag associates the PC and TC with the associated global code for use in creating the indirect PE RVUs. For example, the professional service, CPT code 93010 (Electrocardiogram, routine ECG with at least 12 leads; interpretation and report only), is associated with the global service, CPT code 93000 (Electrocardiogram, routine ECG with at least 12 leads; with interpretation and report).

• Payment modifiers: Payment modifiers are accounted for in the creation of the file consistent with current payment policy as implemented in claims processing. For example, services billed with the assistant at surgery modifier are paid 16 percent of the PFS amount for that service; therefore, the utilization file is modified to only account for 16 percent of any service that contains the assistant at surgery modifier. Similarly, for those services to which volume adjustments are made to account for the payment modifiers, time adjustments are applied as well. For time adjustments to surgical services, the intraoperative portion in the physician time file is used; where it is not present, the intraoperative percentage from the payment files used by contractors to process Medicare claims is used instead. Where neither is available, we use the payment adjustment ratio to adjust the time accordingly. Table 2 details the manner in which the modifiers are applied.

TABLE 2: Application of Payment Modifiers to Utilization Files

Modifier	Description	Volume Adjustment	Time Adjustment
80,81,82	Assistant at Surgery	16%	Intraoperative
			portion

Modifier	Description	Volume Adjustment	Time Adjustment
AS	Assistant at Surgery –	14% (85% * 16%)	Intraoperative
	Physician Assistant		portion
50 or	Bilateral Surgery	150%	150% of physician
LT and RT			time
51	Multiple Procedure	50%	Intraoperative
			portion
52	Reduced Services	50%	50%
53	Discontinued Procedure	50%	50%
54	Intraoperative Care only	Preoperative +	Preoperative +
		Intraoperative	Intraoperative
		Percentages on the	portion
		payment files used by	
		Medicare contractors	
		to process Medicare	
		claims	
55	Postoperative Care only	Postoperative	Postoperative
		Percentage on the	portion
		payment files used by	
		Medicare contractors	
		to process Medicare	
		claims	
62	Co-surgeons	62.5%	50%
66	Team Surgeons	33%	33%

We also make adjustments to volume and time that correspond to other payment rules, including special multiple procedure endoscopy rules and multiple procedure payment reductions (MPPR). We note that section 1848(c)(2)(B)(v) of the Act exempts certain reduced payments for multiple imaging procedures and multiple therapy services from the BN calculation under section 1848(c)(2)(B)(ii)(II) of the Act. These MPPRs are not included in the development of the RVUs.

For anesthesia services, we do not apply adjustments to volume since the average allowed charge is used when simulating RVUs, and therefore, includes all adjustments.

A time adjustment of 33 percent is made only for medical direction of two to four cases since that is the only situation where time units are duplicative.

• Work RVUs: The setup file contains the work RVUs from this final rule with comment period.

(6) Equipment Cost Per Minute

The equipment cost per minute is calculated as:

(1/(minutes per year * usage)) * price * ((interest rate/(1-(1/((1 + interest rate)^
life of equipment)))) + maintenance)

Where:

minutes per year = maximum minutes per year if usage were continuous (that is, usage = 1); generally 150,000 minutes.

usage = variable, see discussion below.

price = price of the particular piece of equipment.

life of equipment = useful life of the particular piece of equipment.

maintenance = factor for maintenance; 0.05.

interest rate = variable, see discussion below.

<u>Usage</u>: We currently use an equipment utilization rate assumption of 50 percent for most equipment, with the exception of expensive diagnostic imaging equipment. For CY 2013, expensive diagnostic imaging equipment, which is equipment priced at over \$1 million (for example, computed tomography (CT) and magnetic resonance imaging (MRI) scanners), we use an equipment utilization rate assumption of 75 percent. Section 1848(b)(4)(C) of the Act, as modified by section 635 of the ATRA), requires that for fee schedules established for CY 2014 and subsequent years, in the methodology for determining PE RVUs for expensive diagnostic imaging equipment, the Secretary shall use a 90 percent assumption. The provision also requires that the reduced expenditures attributable to this change in the utilization rate for CY 2014 and

subsequent years shall not be taken into account when applying the BN limitation on annual adjustments described in section 1848(c)(2)(B)(ii)(II) of the Act. We are applying the 90 percent utilization rate assumption in CY 2014 to all of the services to which the 75 percent equipment utilization rate assumption applied in CY 2013. These services are listed in a file called "CY 2014 CPT Codes Subject to 90 Percent Usage Rate," available on the CMS website under downloads for the CY 2014 PFS final rule with comment period at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html. These codes are also displayed in Table 3.

TABLE 3: CPT Codes Subject to 90 Percent Equipment Utilization Rate Assumption

CPT	
Code	Short Descriptor
70336	Mri, temporomandibular joint(s)
70450	Ct head/brain w/o dye
70460	Ct head/brain w/ dye
70470	Ct head/brain w/o & w/ dye
70480	Ct orbit/ear/fossa w/o dye
70481	Ct orbit/ear/fossa w/ dye
70482	Ct orbit/ear/fossa w/o & w/ dye
70486	Ct maxillofacial w/o dye
70487	Ct maxillofacial w/ dye
70488	Ct maxillofacial w/o & w/ dye
70490	Ct soft tissue neck w/o dye
70491	Ct soft tissue neck w/ dye
70492	Ct soft tissue neck w/o & w/ dye
70496	Ct angiography, head
70498	Ct angiography, neck
70540	Mri orbit/face/neck w/o dye
70542	Mri orbit/face/neck w/ dye
70543	Mri orbit/face/neck w/o & w/dye
70544	Mr angiography head w/o dye
70545	Mr angiography head w/dye
70546	Mr angiography head w/o & w/dye
70547	Mr angiography neck w/o dye
70548	Mr angiography neck w/dye

CPT	
Code	Short Descriptor
70549	Mr angiography neck w/o & w/dye
70551	Mri brain w/o dye
70552	Mri brain w/dye
70553	Mri brain w/o & w/dye
70554	Fmri brain by tech
71250	Ct thorax w/o dye
71260	Ct thorax w/ dye
71270	Ct thorax w/o & w/ dye
71275	Ct angiography, chest
71550	Mri chest w/o dye
71551	Mri chest w/ dye
71552	Mri chest w/o & w/ dye
71555	Mri angio chest w/ or w/o dye
72125	CT neck spine w/o dye
72126	Ct neck spine w/dye
72127	Ct neck spine w/o & w/dye
72128	Ct chest spine w/o dye
72129	Ct chest spine w/dye
72130	Ct chest spine w/o & w/dye
72131	Ct lumbar spine w/o dye
72132	Ct lumbar spine w/dye
72133	Ct lumbar spine w/o & w/dye
72141	Mri neck spine w/o dye
72142	Mri neck spine w/dye
72146	Mri chest spine w/o dye
72147	Mri chest spine w/dye
72148	Mri lumbar spine w/o dye
72149	Mri lumbar spine w/dye
72156	Mri neck spine w/o & w/dye
72157	Mri chest spine w/o & w/dye
72158	Mri lumbar spine w/o & w/dye
72159	Mr angio spone w/o&w/dye
72191	Ct angiography, pelv w/o & w/ dye
72192	Ct pelvis w/o dye
72193	Ct pelvis w/ dye
72194	Ct pelvis w/o & w/ dye
72195	Mri pelvis w/o dye
72196	Mri pelvis w/ dye

CPT	
Code	Short Descriptor
72197	Mri pelvis w/o &w/ dye
72198	Mri angio pelvis w/ or w/o dye
73200	Ct upper extremity w/o dye
73201	Ct upper extremity w/dye
73202	Ct upper extremity w/o & w/dye
73206	Ct angio upper extr w/o & w/dye
73218	Mri upper extr w/o dye
73219	Mri upper extr w/dye
73220	Mri upper extremity w/o & w/dye
73221	Mri joint upper extr w/o dye
73222	Mri joint upper extr w/dye
73223	Mri joint upper extr w/o & w/dye
73225	Mr angio upr extr w/o&w/dye
73700	Ct lower extremity w/o dye
73701	Ct lower extremity w/dye
73702	Ct lower extremity w/o & w/dye
73706	Ct angio lower ext w/o & w/dye
73718	Mri lower extremity w/o dye
73719	Mri lower extremity w/dye
73720	Mri lower ext w/ & w/o dye
73721	Mri joint of lwr extre w/o dye
73722	Mri joint of lwr extr w/dye
73723	Mri joint of lwr extr w/o & w/dye
73725	Mr angio lower ext w or w/o dye
74150	Ct abdomen w/o dye
74160	Ct abdomen w/ dye
74170	Ct abdomen w/o & w/ dye
	Ct angiography, abdomen and pelvis
74174	w/o & w/ dye
	Ct angiography, abdom w/o & w/
74175	dye
74176	Ct abdomen and pelvis w/o dye
74177	Ct abdomen and pelvis w/dye
74178	Ct abdomen and pelvis w/ and w/o
74178	dye Mri abdomen w/o dye
74181	*
74182	Mri abdomen w/ dye Mri abdomen w/o and w/ dye
	Ţ
74185	Mri angio, abdom w/ or w/o dye

CPT	
Code	Short Descriptor
74261	Ct colonography, w/o dye
74262	Ct colonography, w/ dye
75557	Cardiac mri for morph
75559	Cardiac mri w/stress img
75561	Cardiac mri for morph w/dye
75563	Cardiac mri w/stress img & dye
75565	Card mri vel flw map add-on
75571	Ct hrt w/o dye w/ca test
75572	Ct hrt w/3d image
75573	Ct hrt w/3d image, congen
75574	Ct angio hrt w/3d image
75635	Ct angio abdominal arteries
76380	CAT scan follow up study
77058	Mri, one breast
77059	Mri, broth breasts
77078	Ct bone density, axial
77084	Magnetic image, bone marrow

<u>Comment:</u> Several commenters objected to the statutorily-mandated change in equipment utilization rate assumptions, but none provided evidence that CMS has authority to use a different equipment utilization assumption for these services.

Response: As mandated by statute, we are finalizing our proposed change in the equipment utilization rate for these services.

Interest Rate: In the CY 2013 final rule with comment period (77 FR 68902), we updated the interest rates used in developing an equipment cost per minute calculation. The interest rate was based on the Small Business Administration (SBA) maximum interest rates for different categories of loan size (equipment cost) and maturity (useful life). The interest rates are listed in Table 4. (See 77 FR 68902 for a thorough discussion of this issue.)

TABLE 4: SBA Maximum Interest Rates

Price	Useful Life	Interest Rate
<\$25K	<7 Years	7.50%
\$25K to \$50K	<7 Years	6.50%
>\$50K	<7 Years	5.50%
<\$25K	7+ Years	8.00%
\$25K to \$50K	7+ Years	7.00%
>\$50K	7+ Years	6.00%

See 77 FR 68902 for a thorough discussion of this issue.

TABLE 5: Calculation of PE RVUs under Methodology for Selected Codes

	Step	Source	Formula	99213 Office visit, est Non- facility	33533 CABG, arterial, single Facility	71020 Chest x- ray Non- facility	71020- TC Chest x-ray, Non- facility	71020-26 Chest x- ray, Non- facility	93000 ECG, complete, Non- facility	93005 ECG, tracing Non- facility	93010 ECG, report Non- facility
(1) Labor cost (Lab)	Step 1	AMA		13.32	77.52	5.74	5.74	0.00	5.10	5.10	0.00
(2) Supply cost (Sup)	Step 1	AMA		2.98	7.34	3.39	3.39	0.00	1.19	1.19	0.00
(3) Equipment cost (Eqp)	Step 1	AMA		0.17	0.58	7.24	7.24	0.00	0.09	0.09	0.00
(4) Direct cost (Dir)	Step 1		=(1)+(2)+ (3)	16.48	85.45	16.38	16.38	0.00	6.38	6.38	0.00
(5) Direct adjustment (Dir. Adj.)	Steps 2-4	See footnote*		0.5511	0.5511	0.5511	0.5511	0.5511	0.5511	0.5511	0.5511
(6) Adjusted Labor	Steps 2-4	=Lab * Dir Adj	=(1)*(5)	7.34	42.72	3.16	3.16	0.00	2.81	2.81	0.00
(7) Adjusted Supplies	Steps 2-4	=Eqp * Dir Adj	=(2)*(5)	1.64	4.05	1.87	1.87	0.00	0.66	0.66	0.00
(8) Adjusted Equipment	Steps 2-4	=Sup * Dir Adj	=(3)*(5)	0.10	0.32	3.99	3.99	0.00	0.05	0.05	0.00
(9) Adjusted Direct	Steps 2-4		=(6)+(7)+ (8)	9.08	47.09	9.03	9.03	0.00	3.52	3.52	0.00
(10) Conversion Factor (CF)	Step 5	PFS		34.0230	34.0230	34.0230	34.023 0	34.0230	34.0230	34.0230	34.0230
(11) Adj. labor cost converted	Step 5	=(Lab * Dir Adj)/CF	=(6)/(10)	0.22	1.26	0.09	0.09	0.00	0.08	0.08	0.00
(12) Adj. supply cost converted	Step 5	=(Sup * Dir Adj)/CF	=(7)/(10)	0.05	0.12	0.05	0.05	0.00	0.02	0.02	0.00
(13) Adj. equipment cost converted	Step 5	=(Eqp * Dir Adj)/CF	=(8)/(10)	0.00	0.01	0.12	0.12	0.00	0.00	0.00	0.00
(14) Adj. direct cost converted	Step 5		=(11)+(12) +(13)	0.27	1.38	0.27	0.27	0.00	0.10	0.10	0.00

	Step	Source	Formula	99213 Office visit, est Non- facility	33533 CABG, arterial, single Facility	71020 Chest x- ray Non- facility	71020- TC Chest x-ray, Non- facility	71020-26 Chest x- ray, Non- facility	93000 ECG, complete, Non- facility	93005 ECG, tracing Non- facility	93010 ECG, report Non- facility
(15) Work RVU	Setup File	PFS		0.97	33.75	0.22	0.00	0.22	0.17	0.00	0.17
(16) Dir_pct	Steps 6,7	Surveys		0.31	0.18	0.31	0.31	0.31	0.31	0.31	0.31
(17) Ind_pct	Steps 6,7	Surveys		0.69	0.82	0.69	0.69	0.69	0.69	0.69	0.69
(18) Ind. Alloc. Formula (1st part)	Step 8	See Step 8		((14)/(16))*(17)	((14)/(16)) *(17)	((14)/(16))*(17)	((14)/(16))*(1 7)	((14)/(16))*(17)	((14)/(16))*(17)	((14)/(16))*(17)	((14)/(16))*(17)
(19) Ind. Alloc.(1st part)	Step 8		See 18	0.81	6.51	0.65	0.65	0	0.26	0.26	0
(20) Ind. Alloc. Formula (2nd part)	Step 8	See Step 8		(15)	(15)	(15+11)	(11)	(15)	(15+11)	(11)	(15)
(21) Ind. Alloc.(2nd part)	Step 8		See 20	0.97	33.75	0.31	0.09	0.22	0.25	0.08	0.17
(22) Indirect Allocator (1st + 2nd)	Step 8		=(19)+ (21)	1.78	40.26	0.96	0.74	0.22	0.51	0.34	0.17
(23) Indirect Adjustment (Ind. Adj.)	Steps 9-11	See Footnote**		0.3848	0.3848	0.3848	0.3848	0.3848	0.3848	0.3848	0.3848
(24) Adjusted Indirect Allocator	Steps 9-11	=Ind Alloc * Ind Adj		0.68	15.49	0.37	0.29	0.08	0.20	0.13	0.07
(25) Ind. Practice Cost Index (IPCI)	Steps 12- 16			1.07	0.76	0.95	0.95	0.95	0.91	0.91	0.91
(26) Adjusted Indirect	Step 17	= Adj.Ind Alloc * PCI	=(24)*(25)	0.73	11.74	0.35	0.27	0.08	0.18	0.12	0.06
(27) PE RVUs in	Step 18	=(Adj Dir + Adj Ind) * Other Adj	=((14)+ (26)) * Other Adj)	1.00	13.08	0.63	0.55	0.08	0.28	0.22	0.06

Note: PE RVUs in Table 5, row 27, may not match Addendum B due to rounding.

Step	Source	Formula	99213	33533	71020	71020-	71020-26	93000	93005	93010
			Office	CABG,	Chest x-	TC	Chest x-	ECG,	ECG,	ECG,
			visit, est	arterial,	ray	Chest	ray,	complete,	tracing	report
			Non-	single	Non-	x-ray,	Non-	Non-	Non-	Non-
			facility	Facility	facility	Non-	facility	facility	facility	facility
						facility				

^{*}The direct adj = [current pe rvus * CF * avg dir pct]/[sum direct inputs] = [step2]/[step3]

Note: The use of any particular conversion factor (CF) in Table 5 to illustrate the PE Calculation has no effect on the resulting RVUs.

Note: The Other Adjustment includes an adjustment for the equipment utilization change.

^{**}The indirect adj = [current pe rvus * avg ind pct]/[sum of ind allocators] = [step9]/[step10]

3. Adjusting RVUs to Match PE Share of the Medicare Economic Index (MEI)

For CY 2014, as explained in detail in section II.D of this final rule with comment period, we are finalizing revisions to the MEI based on the recommendations of the MEI Technical Advisory Panel (TAP). The MEI is an index that measures the price change of the inputs used to furnish physician services. This measure was authorized by statute and is developed by the CMS Office of the Actuary. We believe that the MEI is the best measure available of the relative weights of the three components in payments under the PFS – work, PE and malpractice. Accordingly, we believe that to assure that the PFS payments reflect the resources in each of these components as required by section 1848(c)(3) of the Act, the RVUs used in developing rates should reflect the same weights in each component as the MEI. We proposed to accomplish this by holding the work RVUs constant and adjusting the PE RVUs, the MP RVUs and the CF to produce the appropriate balance in RVUs among components and payments. In the proposed rule and above, we detailed the steps necessary to accomplish this result (see steps 3, 10, and 18).

This proposed adjustment is consistent with our longstanding practice to make adjustments to match the RVUs for the PFS components with the MEI cost share weights for the components, including the adjustments described in the CY 1999 PFS Final Rule (63 FR 58829), CY 2004 PFS Final Rule 68 FR 63246-63247, and CY 2011 PFS Final Rule (75 FR 73275). We note that the revisions to the MEI finalized in section II.D of this final rule are made to the MEI as rebased for CY 2011, and that the RVUs we proposed for CY 2014 reflect the weights of the MEI as rebased for CY 2011 and revised for CY 2014. As such, the relationships among the work, PE, and malpractice RVUs under the PFS are aligned with those under the revised 2006-based MEI.

<u>Comment:</u> Several commenters requested explanation regarding the relationship between the proposed MEI revision and the proposed RVUs. One commenter suggested that it would be better to scale the work RVUs upward instead of scaling the PE RVUs downward to achieve the weighting adjustment.

Response: The change in the relationship among work, PE, and malpractice RVUs could be accomplished by applying adjustments directly to the work, PE, and malpractice RVUs or by holding the RVUs constant for one component, scaling the other two components and applying a budget neutrality adjustment to the conversion factor. We proposed to make the adjustment by holding work RVUs constant consistent with prior adjustments and in response to many public comments made during previous rulemaking (see, for example, 75 FR 73275) indicating a strong preference and persuasive arguments in favor of keeping the work RVUs stable over time since work RVUs generally only change based on reviews of particular services. In contrast, PE RVUs are developed annually, irrespective of changes in the direct PE inputs for particular services, so that scaling of PE RVUs is less disruptive to the public review of values that determine PFS payment rates. We took this approach for the CY 2014 adjustment because we believe the methodology and reasons for making the adjustment in this way are settled and remain valid. For these reasons, we are finalizing the proposed rebasing of the relationship among RVU components by holding the work RVUs constant, decreasing the PE RVUs and the MP RVUs, and applying a budget neutrality adjustment to the CF.

<u>Comment:</u> Several commenters argued that the RVU components should not be weighted consistent with the revised MEI as it was it was entirely appropriate to include

nurse practitioner and physician assistant wages in the physician practice expense calculation because physicians often employ nurse practitioners, physician assistants and

other non-physicians.

Response: We refer commenters to section II.D. of the final rule with comment period regarding the appropriate classification of wages in the MEI. Regarding classification of labor inputs in the RVU components, the decision as to whether something should be considered a practice expense or work under the PFS does not depend on the employment status of the health care professional furnishing the service. Resource inputs are classified based on whether they relate to the "work" or "practice expense" portion of a service. The clinical labor portion of the direct PE input database includes the portion of services provided by practitioners who do not bill Medicare directly, such as registered nurses and other clinical labor. We do not include in this category the costs of nurse practitioners and others who can bill Medicare directly. Under the PFS, the work component of a service is valued based on the work involved in furnishing the typical service. The value is the same whether the service is billed by a physician or another practitioner (such as a nurse practitioner or physician assistant) who is permitted to bill Medicare directly for the service. We acknowledge that these practitioners may perform a variety of services in a physician office – some of which would be included in the work portion and others that would be included in the PE portion as clinical labor. Similarly, it is not unusual for physicians to hire other

physicians to work in their practices, but we likewise do not consider those costs to be part of the clinical labor that is included as a practice expense. Since values for services under the PFS are based upon the typical case rather than the type of practitioner that performs the service in a particular situation, we continue to believe it is appropriate to include the work performed by professionals eligible to bill Medicare directly in the work component of PFS payments, even in cases when they are employed by physicians.

Additionally, we note that none of the commenters who questioned the appropriate accounting for the work of these nonphysician practitioners addressed how it would be appropriate to treat the costs for these nonphysician practitioners differently for purposes of calculating RVUs and the MEI. The labor of nonphysician practitioners who can bill independently for their services under the PFS is considered as work under the physician fee schedule since these services are also furnished by physicians and the RVUs for these PFS services do not vary based on whether furnished by a physician or nonphysician. As such, we believe that the change in the MEI to shift these costs from the PE to the work category as described in section II.D. of this final rule with comment period is entirely consistent with the PFS in this regard.

We would also note that the change in the MEI was recommended by the MEI TAP that identified a discrepancy between how the work of non-physician practitioners is captured in the RVUs, how billing works under the PFS, and how costs are accounted for in the MEI. With the change in the MEI being finalized in this final rule with comment period, we continue to believe that the MEI weights are the best reflection of the PFS component weights, and we believe it is appropriate to finalize this adjustment in the RVUs as well.

Comment: Several commenters strongly urged the agency, in adjusting weights among the PFS components to reflect the MEI cost weight changes, to consider alternative methodologies that would mitigate the redistribution of RVUs from the PE to the work category. These commenters pointed out that the practitioners who furnish services with a higher proportion of PE RVUs are hit hardest by these changes. These comments also suggested that CMS should consider postponing this adjustment of the RVUs until such a methodology can be vetted.

Several commenters suggested that, given the magnitude of the reductions, CMS should consider a phase-in of this change. These commenters pointed out that CMS has used a phase-in approach in the past to mitigate the effects of methodological changes to the calculation of payment rates under the MPFS, including a four-year phase-in of the transition from the top-down to the bottom-up methodology of calculating direct PE RVUs.

Response: We appreciate that the increase in the work RVUs relative to PE RVUs will generally result in lower payments for practitioners who furnish more services with a higher proportion of PE RVUs. However, we continue to believe that the MEI cost share weights are the best reflection of the PFS component weights. The CY 2014 revisions to the MEI, following the rebasing for 2011 and consideration by the MEI TAP, reflect the best available information. As such, we believe that the relationship among the RVU components should conform to the revised cost weights adopted for the MEI.

While we understand and recognize the general preference to avoid significant year-toyear reductions in Medicare payment, including practitioners' interests in phasing in any reduction, and we acknowledge that this revision of the PFS component weights results in an increase in work RVUs relative to PE RVUs, we note that the 2011 rebasing of the MEI resulted

in a change of greater magnitude that increased the PE RVUs relative to work RVUs. That change was not phased in. Based on consideration of these comments, we are finalizing as proposed the adjustment to the relationship among the work, PE, and malpractice component RVUs to reflect the MEI cost share being finalized in this final rule with comment period, with the necessary adjustment to the conversion factor and to PE and MP RVUs to maintain budget neutrality.

4. Changes to Direct PE Inputs for Specific Services

In this section, we discuss other CY 2014 proposals and revisions related to direct PE inputs for specific services. The final direct PE inputs are included in the final rule with comment period CY 2014 direct PE input database, which is available on the CMS website under under downloads for the CY 2014 PFS final rule with comment period at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.

a. Anomalous Supply Inputs

In the CY 2013 PFS final rule with comment period, we established interim final direct PE inputs based on acceptance, with refinement, of recommendations submitted by the AMA RUC. Although we generally address public comments on the current year's interim final direct PE inputs in the following year's final rule with comment period, several commenters raised an issue regarding anomalous supply items for codes that were not subject to comment in the CY 2013 final rule with comment period. Since changes were being suggested to codes not subject to comment, we believed these comments were best addressed through proposed revisions to the direct PE inputs in the proposed rule allowing the opportunity for public comment before implementation.

For the CY 2013 interim final direct PE inputs for a series of codes that describe six levels of surgical pathology services (CPT codes 88300, 88302, 88304, 88305, 88307, 88309), we did not accept the AMA RUC recommendation to create two new direct PE supply inputs because we did not consider these items to be disposable supplies (77 FR 69074) and thus they did not meet the criteria for direct PE inputs. These items were called "specimen, solvent, and formalin disposal cost," and "courier transportation costs." In the CY 2013 PFS final rule with comment period, we explained that neither the specimen and supply disposal nor courier costs for transporting specimens are appropriately considered disposable medical supplies. Instead, we stated these costs are incorporated into the PE RVUs for these services through the indirect PE allocation. We also noted that the current direct PE inputs for these and similar services across the PFS do not include these kinds of costs as disposable supplies.

Several commenters noted that, contrary to our assertion in the CY 2013 final rule with comment period, there are items incorporated in the direct PE input database as "supplies" that are no more disposable supplies than the new items recommended by the AMA RUC for the surgical pathology codes. These commenters identified seven supply inputs in particular that they believe are analogous to the items that we did not accept in establishing CY 2013 interim final direct PE inputs. These items and their associated HCPCS codes are listed in Table 6.

TABLE 6: Items Identified by Commenters

CMS Supply Code	Item Description	Affected CPT Codes
SK106	device shipping cost	93271, 93229, 93268
SK112	Federal Express cost (average across all zones)	64650, 88363, 64653
SK113	communication, wireless per service	93229
SK107	fee, usage, cycletron/accelerator, gammaknife, Lincac SRS System	77423, 77422
SK110	fee, image analysis	96102, 96101, 99174

CMS Supply Code	Item Description	Affected CPT Codes
SK111	fee, licensing, computer, psychology	96102, 96101, 96103, 96120
SD140	bag system, 1000ml (for angiographywaste fluids)	93451,93452,93453,93454, 93455,93456,93457,93458, 93459,93460,93461

We reviewed each of these items for consistency with the general principles of the PE methodology regarding the categorization of all costs. Within the PE methodology, all costs other than clinical labor, disposable supplies, and medical equipment are considered indirect costs. For six of the items contained in Table 6, we agreed with the commenters that the items should not be considered disposable supplies. We believed that these items are more appropriately categorized as indirect PE costs, which are reflected in the allocation of indirect PE RVUs rather than through direct PE inputs. Therefore, we proposed to remove the following six items from the direct PE input database for CY 2014: "device shipping cost" (SK106); "Federal Express cost (average across all zones)" (SK112); "communication, wireless per service" (SK113); "fee, usage, cycletron/accelerator, gammaknife, Lincac SRS System" (SK107); "fee, image analysis" (SK110); and "fee, licensing, computer, psychology" (SK111).

In the case of the supply item called "bag system, 1000ml (for angiography waste fluids)" (SD140), we did not agree with the commenters that this item is analogous to the specimen disposal costs recommended for the surgical pathology codes. This supply input represents only the costs of the disposable material items associated with the removal of waste fluids that typically result from a particular procedure. In contrast, the item recommended by the AMA RUC for surgical pathology consisted of an amortized portion of a specimen disposal contract that includes costs for resources such as labor and transportation. Furthermore, we did not believe that the specimen disposal contract is attributable to individual procedures within the

established PE methodology. We believe that a disposable supply is one that is attributable, in its entirety, to an individual patient for a particular service. An amortized portion of a specimen disposal contract does not meet these criteria. Accordingly, as stated in the CY 2013 final rule with comment period, we did not accept the AMA RUC recommendation to create a new supply item related to specimen disposal costs. We believe that many physician offices and other nonfacility settings where Medicare beneficiaries receive services incur costs related to waste management or other service contracts, but none of these costs are currently incorporated into the PE methodology as disposable supplies. Instead, these costs are appropriately categorized as indirect costs, which are reflected in the PE RVUs through the allocation of indirect PE. We clarified that we believe that supply costs related to specimen disposal attributable to individual services may be appropriately categorized as disposable supplies, but that specimen disposal costs related to an allocated portion of service contracts cannot be attributed to individual services and should not be incorporated into the direct PE input database as disposable supplies.

Moreover, because we do not agree with commenters that the "bag system, 1000ml (for angiography waste fluids)" (SD140) is analogous to a specimen disposal contract for the reasons state above, we continued to believe that SD140 is a direct expense. Accordingly, we did not propose to remove SD140 from the direct PE input database.

<u>Comment:</u> One commenter objected to CMS's proposal to remove the "device shipping cost" (SK106) and "communication, wireless per service" (SK113) from the direct PE input database as they are more analogous to the angiography waste fluid bag system than the other items since both items represent costs associated with a specific procedure rather than an amortization of costs associated with a service contract.

Response: We agree with the commenter that both of these items may represent costs

associated with a specific procedure. However, as we articulated in making the proposal to remove these items, we do not believe these items are disposable supplies and we believe all costs other than clinical labor, disposable supplies, and medical equipment should be considered indirect costs in order to maintain consistency and relativity within the PE methodology. We believe that there are a variety of costs allocable to individual services that are appropriately considered part of indirect cost categories for purposes of the PE methodology. Were all these included as direct PE inputs for services across the PFS, regardless of whether or not the items were reasonably described as clinical labor, disposable supplies, or medical equipment, then the relationship between direct and indirect costs would be significantly skewed. This skewing could be compounded since the amount of indirect PE allocated to particular codes is partly determined by the amount of direct costs associated with the codes. Therefore, the inaccurate inclusion of indirect costs as direct costs would not only result in duplicative accounting for the items (as both indirect and direct PE costs) but also an additional allocation of indirect PE based on the item's inclusion as a direct cost. Therefore, we are finalizing removal of these items from the direct PE input database as proposed.

Comment: Several commenters suggested that CMS should change its understanding of direct and indirect practice expense items. One commenter suggested that all variable costs proportional to the number of services furnished per day be considered direct. Another commenter suggested that the only costs that can be considered indirect costs are those that are required by all services, those that do not vary from one service type to the next; and those that are not based on service volume. Therefore CMS should allow all other recommended direct PE inputs to be allowed as direct PE inputs.

Response: We note that there is a longstanding PE methodology, established through

notice and comment rulemaking that includes principles for determining whether an expense is direct or indirect. Under the established PE methodology, whether or not a particular cost is variable has little bearing on the appropriate classification of a particular item as a direct or indirect cost. Although we have previously pointed out that the current methodology does not accommodate costs that cannot be allocated to particular services as direct costs, this does not mean that all costs that can be allocated to particular services are necessarily direct costs. Instead, a significant number of costs considered to be indirect for purposes of the PE methodology are variable costs proportional to the kind and number of services furnished each day. For example, administrative and clerical resource costs associated with medical billing are likely to be incurred with each service furnished. Presumably, practitioners incur greater resource cost associated with administrative and clerical labor and supplies based on the volume of services furnished. Similarly, some kinds of services may require more administrative resources than others. Some complex services, for example, may require advance or follow-up administrative work that is not required for less complex services. General office expenses may also vary depending on the number and kind of services furnished. For example, practices that furnish a greater number of services to a greater number of patients generally require larger waiting rooms and additional waiting room furniture. Other services such as those that are furnished without having the patient present may not require patient waiting rooms at all. We note that some services require a different amount of electricity than others and some require more space than others. We believe that the PE methodology accounts for these costs in the allocation of indirect PE RVUs included in the payment rate for each service furnished to Medicare beneficiaries. We do not believe it would appropriate in the current methodology to include all such variable costs as direct PE inputs. Therefore, we do not agree with commenters'

assertions regarding the appropriateness of these items as direct costs. Instead, we continue to believe that these costs represent indirect costs that are incorporated in the PE RVUs for these services through the allocation of indirect PE RVUs. We also direct readers to section II.E.2.b. of this final rule for a discussion of comments received regarding the CY 2013 interim final direct PE inputs for surgical pathology services.

After consideration of these comments, we are finalizing our proposal to remove the specified anomalous supply items from the direct PE input database. The CY 2014 direct PE input database and the PE RVUs displayed in Addendum B of this final rule with comment period reflect the finalization of this proposal.

b. Direct PE Input Refinements based on Routine Data Review

In reviewing the direct PE input database, we identified several discrepancies that we proposed to address for CY 2014. In the following paragraphs, we identify the nature of these discrepancies, the affected codes, and the adjustments proposed in the CY 2014 proposed rule direct PE input database. As part of our internal review of information in the direct PE input database, we identified supply items that appeared without quantities for CPT code 51710 (Change of cystostomy tube; complicated). Upon reviewing these items we believed that the code should include the items at the quantities listed in Table 7.

TABLE 7: Supply Items and Quantities for CPT code 51710

Supply Code	Description of Supply Item	NF Quantity
SA069	tray, suturing	1.0
SB007	drape, sterile barrier 16in x 29in	1.0
SC029	needle, 18-27g	1.0
SC051	syringe 10-12ml	1.0
SD024	catheter, Foley	1.0
SD088	Guidewire	1.0

Supply Code	Description of Supply Item	NF Quantity
SF036	suture, nylon, 3-0 to 6-0, c	1.0
SG055	gauze, sterile 4in x 4in	1.0
SG079	tape, surgical paper 1 in (Micropore)	6.0
SH075	water, sterile inj	3.0
SJ032	lubricating jelly (K-Y) (5gm uou)	1.0
SJ041	povidone soln (Betadine)	20.0

Upon reviewing the direct PE inputs for CPT code 51710 and the related code 51705 (Change of cystostomy tube; simple), we also noted that the direct PE input database includes an anomalous 0.5 minutes of clinical labor time in the post-service period. We believe that this small portion of clinical labor time is the result of a rounding error in our data and should be removed from the direct PE input database.

<u>Comment</u>: One commenter supported the inclusion of the supply items for CPT code 51710. We received no comments regarding the change in clinical labor time for codes 51710 and 51705.

Response: Based on these comments and for the reasons stated, we are finalizing the removal of these items in the CY 2014 final direct PE input database.

During our review of the data, we noted an invalid supply code (SM037) that appears in the direct PE input database for CPT codes 88312 and 88313. Upon review of the code, we believe that the supply item called "wipes, lens cleaning (per wipe) (Kimwipe)" (SM027) should be included for these codes instead of the invalid supply code. We did not receive any comments regarding this proposed revision. Therefore, we are finalizing this revision as proposed for CY 2014.

Additionally, we conducted a routine review of the codes valued in the nonfacility setting for which moderate sedation is inherent in the procedure. Consistent with the standard moderate

sedation package finalized in the CY 2012 PFS final rule with comment period (76 FR 73043), we have made minor adjustments to the nurse time and equipment time for 18 of these codes. These codes appear in Table 8.

<u>Comment:</u> One commenter agreed with this proposal to standardize moderate sedation inputs for codes valued in the nonfacility setting. We received no comments on the correction on the invalid supply item.

Response: After considering this comment, we are finalizing the minor adjustments to the moderate sedation inputs as proposed. The CY 2014 direct PE database reflects these adjustments.

TABLE 8: Codes with Minor Adjustments to Moderate Sedation Inputs

CPT Code	Descriptor
31629	Bronchoscopy/needle bx each
31645	Bronchoscopy clear airways
31646	Bronchoscopy reclear airway
32405	Percut bx lung/mediastinum
32550	Insert pleural cath
35471	Repair arterial blockage
37183	Remove hepatic shunt (tips)
37210	Embolization uterine fibroid
43453	Dilate esophagus
43458	Dilate esophagus
44394	Colonoscopy w/snare
45340	Sig w/balloon dilation
47000	Needle biopsy of liver
47525	Change bile duct catheter
49411	Ins mark abd/pel for rt perq
50385	Change stent via transureth
50386	Remove stent via transureth
57155	Insert uteri tandem/ovoids
93312	Echo transesophageal
93314	Echo transesophageal
G0341	Percutaneous islet celltrans

c. Adjustments to Pre-Service Clinical Labor Minutes

As we noted in the CY 2014 PFS proposed rule, we had recently received a recommendation from the AMA RUC regarding appropriate pre-service clinical labor minutes in the facility setting for codes with 000-day global periods. In general, the AMA RUC recommended that codes with 000-day global period include a maximum of 30 minutes of clinical labor time in the pre-service period in the facility setting. The AMA RUC identified 48 codes that currently include more clinical labor time than this recommended maximum and provided us with recommended pre-service clinical labor minutes in the facility setting of 30 minutes or fewer for these 48 codes. We reviewed the AMA RUC's recommendation and agree that the recommended reductions would be appropriate to maintain relativity with other 000-day global codes. Therefore, we proposed to amend the pre-service clinical labor minutes for the codes listed in Table 9, consistent with the AMA RUC recommendation.

<u>Comment:</u> One commenter supported this proposal based on the AMA RUC's recommendation.

<u>Response:</u> After considering the supporting comment, we are finalizing these changes as proposed. The CY 2014 direct PE input database reflects these changes.

TABLE 9: 000-Day Global Codes with Changes to Pre-service CL Time

CPT Code	Short Descriptor	Existing CL Pre- Service Facility Minutes	CL Pre-Service Facility Minutes (AMA RUC Recommendation)
20900	Removal of bone for graft	60	30
20902	Removal of bone for graft	60	30
33224	Insert pacing lead & connect	35	30
33226	Reposition l ventric lead	35	30
36800	Insertion of cannula	60	0
36861	Cannula declotting	37	0

CPT Code	Short Descriptor	Existing CL Pre- Service Facility Minutes	CL Pre-Service Facility Minutes (AMA RUC Recommendation)
37202	Transcatheter therapy infuse	45	0
50953	Endoscopy of ureter	60	30
50955	Ureter endoscopy & biopsy	60	30
51726	Complex cystometrogram	41	30
51785	Anal/urinary muscle study	34	30
52250	Cystoscopy and radiotracer	37	30
52276	Cystoscopy and treatment	32	30
52277	Cystoscopy and treatment	37	30
52282	Cystoscopy implant stent	31	30
52290	Cystoscopy and treatment	31	30
52300	Cystoscopy and treatment	36	30
52301	Cystoscopy and treatment	36	30
52334	Create passage to kidney	31	30
52341	Cysto w/ureter stricture tx	42	30
52342	Cysto w/up stricture tx	42	30
52343	Cysto w/renal stricture tx	42	30
52344	Cysto/uretero stricture tx	55	30
52345	Cysto/uretero w/up stricture	55	30
52346	Cystouretero w/renal strict	55	30
52351	Cystouretero & or pyeloscope	45	30
52352	Cystouretero w/stone remove	50	30
52353	Cystouretero w/lithotripsy	50	30
52354	Cystouretero w/biopsy	50	30
52355	Cystouretero w/excise tumor	50	30
54100	Biopsy of penis	33	30
61000	Remove cranial cavity fluid	60	15
61001	Remove cranial cavity fluid	60	15
61020	Remove brain cavity fluid	60	15
61026	Injection into brain canal	60	15
61050	Remove brain canal fluid	60	15
61055	Injection into brain canal	60	15
61070	Brain canal shunt procedure	60	15
62268	Drain spinal cord cyst	36	30

CPT Code	Short Descriptor	Existing CL Pre- Service Facility Minutes	CL Pre-Service Facility Minutes (AMA RUC Recommendation)
67346	Biopsy eye muscle	42	30
68100	Biopsy of eyelid lining	32	30
93530	Rt heart cath congenital	35	30
93531	R & I heart cath congenital	35	30
93532	R & I heart cath congenital	35	30
93533	R & I heart cath congenital	35	30
93580	Transcath closure of asd	35	30
93581	Transcath closure of vsd	35	30

d. Price Adjustment for Laser Diode

As we noted in the CY 2013 PFS proposed rule, it has come to our attention that the price associated with the equipment item called "laser, diode, for patient positioning (Probe)" (ER040) in the direct PE input database is \$7,678 instead of \$18,160 as listed in the CY 2013 PFS final rule with comment period (77 FR 68922). We proposed to revise the direct PE input database to reflect the corrected price.

Comment: Several commenters expressed support for this proposal.

Response: We appreciate the commenters' support and have revised the CY 2014 final direct PE input database as proposed.

e. Direct PE Inputs for Stereotactic Radiosurgery (SRS) Services (CPT Codes 77372 and 77373)

Since 2001, Medicare has used HCPCS G-codes, in addition to the CPT codes, for stereotactic radiosurgery (SRS) to distinguish robotic and non-robotic methods of delivery. Based on our review of the current SRS technology, it is our understanding that most services currently furnished with linac-based SRS technology, including services currently billed using the non-robotic codes, incorporate some type of robotic feature. Therefore, we believe that it is

no longer necessary to continue to distinguish robotic versus non-robotic linac-based SRS through the HCPCS G-codes. For purposes of the hospital outpatient prospective payment system (OPPS), we proposed to replace the existing four SRS HCPCS G-codes G0173 (Linear accelerator based stereotactic radiosurgery, complete course of therapy in one session), G0251(Linear accelerator based stereotactic radiosurgery, delivery including collimator changes and custom plugging, fractionated treatment, all lesions, per session, maximum five sessions per course of treatment), G0339 (Image-guided robotic linear accelerator-based stereotactic radiosurgery, complete course of therapy in one session or first session of fractionated treatment), and G0340 (Image-guided robotic linear accelerator-based stereotactic radiosurgery, delivery including collimator changes and custom plugging, fractionated treatment, all lesions, per session, second through fifth sessions, maximum five sessions per course of treatment), with the SRS CPT codes 77372 (Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cranial lesion(s) consisting of 1 session; linear accelerator based) and 77373 (Stereotactic body radiation therapy, treatment delivery, per fraction to 1 or more lesions, including image guidance, entire course not to exceed 5 fractions) that do not distinguish between robotic and non-robotic methods of delivery. We refer readers to section II.C.3 of the CY 2014 OPPS proposed rule for more discussion of that proposal. We also refer readers to the CY 2007 OPPS final rule (71 FR 68023 through 68026) for a detailed discussion of the history of the SRS codes.

Two of the four current SRS G-codes are paid in the nonfacility setting through the PFS. These two codes, G0339 and G0340, describe robotic SRS treatment delivery and are contractor-priced. CPT codes 77372 and 77373, which describe SRS treatment delivery without regard to the method of delivery, are currently paid in the nonfacility setting based on resource-based

RVUs developed through the standard PE methodology. We noted in the proposed rule that if the CY 2014 OPPS proposal were finalized, it would appear that there would no longer be a need for G-codes to describe robotic SRS treatment and delivery. We did not propose to replace the contractor-priced G-codes for PFS payment but did seek comment from the public and stakeholders, including the AMA RUC, regarding whether or not the direct PE inputs for CPT codes 77372 and 77373 would continue to accurately estimate the resources used in furnishing typical SRS delivery were there no coding distinction between robotic and non-robotic methods of delivery.

Comment: Several commenters, including the AMA RUC, responded to our request for information regarding whether the direct PE inputs for CPT codes 77372 and 77373 would continue to accurately estimate the resources used in furnishing typical SRS delivery were there no coding distinction between robotic and non-robotic methods of delivery. Most commenters, including the AMA RUC, stated that the most recently recommended direct PE inputs for these services would accurately estimate the resources. One commenter suggested this was not the case and that CMS should maintain the G-codes for purposes of PFS payment.

Response: We appreciate stakeholders' responsiveness to our request for information.

We will consider the information submitted in public comments as we consider future rulemaking for these codes.

2. Using OPPS and ASC Rates in Developing PE RVUs

We typically establish two separate PE RVUs for services that can be furnished in either a nonfacility setting, like a physician's office, or a facility setting, like a hospital. The nonfacility PE RVUs reflect all of the direct and indirect practice expenses involved in furnishing a particular service when the entire service is furnished in a nonfacility setting. The

facility PE RVUs reflect the direct and indirect practice expenses associated with furnishing a particular service in a setting such as a hospital or ASC where those facilities incur a portion or all of the costs and receive a separate Medicare payment for the service.

When services are furnished in the facility setting, such as a HOPD or an ASC, the total combined Medicare payment (made to the facility and the professional) typically exceeds the Medicare payment made for the same service when furnished in the physician office or other nonfacility setting. We believe that this payment difference generally reflects the greater costs that facilities incur than those incurred by practitioners furnishing services in offices and other nonfacility settings. For example, hospitals incur higher overhead costs because they maintain the capability to furnish services 24 hours a day and 7 days per week, generally furnish services to higher acuity patients than those who receive services in physicians' offices, and have additional legal obligations such as complying with the Emergency Medical Treatment and Labor Act (EMTALA). Additionally, hospitals must meet conditions of participation and ASCs must meet conditions for coverage in order to participate in Medicare.

However, we have found that for some services, the total Medicare payment when the service is furnished in the physician office setting exceeds the total Medicare payment when the service is furnished in an HOPD or an ASC. When this occurs, we believe it is not the result of appropriate payment differentials between the services furnished in different settings. Rather, we believe it is due to anomalies in the data we use under the PFS and in the application of our resource-based PE methodology to the particular services.

The PFS PE RVUs rely heavily on the voluntary submission of information by individuals furnishing the service and who are paid at least in part based on the data provided.

Currently, we have little means to validate whether the information is accurate or reflects typical

resource costs. Furthermore, in the case of certain direct costs, like the price of high-cost disposable supplies and expensive capital equipment, even voluntary information has been very difficult to obtain. In some cases the PE RVUs are based upon single price quotes or one paid invoice. We have addressed these issues extensively in previous rulemaking (for example, 75 FR 73252). Such incomplete, small sample, potentially biased or inaccurate resource input costs may distort the resources used to develop nonfacility PE RVUs used in calculating PFS payment rates for individual services.

In addition to the accuracy issues with some of the physician PE resource inputs, the data used in the PFS PE methodology can often be outdated. As we have previously noted (77 FR 68921) there is no practical means for CMS or stakeholders to engage in a complete simultaneous review of the input resource costs for all HCPCS codes paid under the PFS on an annual or even regular basis. Thus, the information used to estimate PE resource costs for PFS services is not routinely updated. Instead, we strive to maintain relativity by reviewing at the same time the work RVUs, physician time, and direct PE inputs for a code, and reviewing all codes within families of codes where appropriate. Nonetheless, outdated resource input costs may distort RVUs used to develop nonfacility PFS payment rates for individual services. In the case of new medical devices for which a high growth in the volume of a service as it diffuses into clinical practice may lead to a decrease in the cost of expensive items, outdated price inputs can result in significant overestimation of resource costs.

Such inaccurate resource input costs may distort the nonfacility PE RVUs used to calculate PFS payment rates for individual services. As we have previously noted, OPPS payment rates are based on auditable hospital data and are updated annually. Given the differences in the validity of the data used to calculate payments under the PFS and OPPS, we

believe that the nonfacility PFS payment rates for procedures that exceed those for the same procedure when furnished in a facility result from inadequate or inaccurate direct PE inputs, especially in price or time assumptions, as compared to the more accurate OPPS data. On these bases, we proposed a change in the PE methodology beginning in CY 2014. To improve the accuracy of PFS nonfacility payment rates for each calendar year, we proposed to use the current year OPPS or ASC rates as a point of comparison in establishing PE RVUs for services under the PFS. In setting PFS rates, we proposed to compare the PFS payment rate for a service furnished in an office setting to the total combined Medicare payment to practitioners and facilities for the same service when furnished in a hospital outpatient setting. For services on the ASC list, we proposed to make the same comparison except we would use the ASC rate as the point of comparison instead of the OPPS rate.

We proposed to limit the nonfacility PE RVUs for individual codes so that the total nonfacility PFS payment amount would not exceed the total combined amount that Medicare would pay for the same code in the facility setting. That is, if the nonfacility PE RVUs for a code would result in a higher payment than the corresponding combined OPPS or ASC payment rate and PFS facility PE RVUs (when applicable) for the same code, we would reduce the nonfacility PE RVU rate so that the total nonfacility payment does not exceed the total Medicare payment made for the service in the facility setting. To maintain the greatest consistency and transparency possible, we proposed to use the current year PFS conversion factor. Similarly, we proposed to use current year OPPS or ASC rates in the comparison.

For services with no work RVUs, we proposed to compare the total nonfacility PFS payment to the OPPS payment rates directly since no PFS payment is made for these services when furnished in the facility setting.

We proposed to exempt the following services from this policy:

• Services Without Separate OPPS Payment Rates: We proposed to exclude services without separately payable OPPS rates from this methodical change since there would be no OPPS rate to which we could compare the PFS nonfacility PE RVUs. We note that there would also be no ASC rate for these services since ASCs are only approved to furnish a subset of OPPS services.

- Codes Subject to the DRA Imaging Cap: We proposed to exclude from this policy services capped at the OPPS payment rate in accordance with the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109–171). The DRA provision limits PFS payment for most imaging procedures to the amount paid under the OPPS system. This policy applies to the technical component of imaging services, including X-ray, ultrasound, nuclear medicine, MRI, CT, and fluoroscopy services. Screening and diagnostic mammograms are exempt. Since payment for these procedures is capped by statute we proposed to exclude them from this policy.
- <u>Codes with Low Volume in the OPPS or ASC</u>: We proposed to exclude any service for which 5 percent or less of the total number of services are furnished in the OPPS setting relative to the total number of PFS/OPPS allowed services.
- Codes with ASC Rates Based on PFS Payment Rates: To avoid issues of circularity, we proposed to exclude ASC services that are subject to the "office-based" procedure payment policies for which payment rates are based on the PFS nonfacility PE RVUs. We directed interested readers to the CY 2013 OPPS final rule (77 FR 68444) for additional information regarding this payment policy.
- <u>Codes Paid in the Facility at Nonfacility PFS Rates</u>: To avoid issues of circularity, we also proposed to exclude services that are paid in the facility setting at nonfacility payment rates.

This would include certain professional-only services where the resource costs for practitioners are assumed to be similar in both settings.

• <u>Codes with PE RVUs Developed Outside the PE Methodology</u>: We also proposed to exclude services with PE RVUs established through notice and comment rulemaking outside the PE Methodology.

Addendum B of the proposed rule displayed the PE RVUs that would result from implementation of the proposed change in the PE methodology.

In discussing resource input issues, some stakeholders have previously suggested that the direct costs (for example, clinical labor, disposable supplies and medical equipment) involved in furnishing a service are similar in both the nonfacility and facility settings. Others have suggested that facilities, like hospitals, have greater purchasing power for medical equipment and disposable supplies so that the direct costs for a facility to furnish a service can be lower than costs for a physician practice furnishing the same service. Our proposed policy did not assume that the direct costs to furnish a service in the nonfacility setting are always lower than in the facility setting. Medicare payment methodologies, including both OPPS and the PFS PE methodology, incorporate both direct and indirect costs (administrative labor, office expenses, and all other expenses). Our proposed policy was premised on the idea that there are significantly greater indirect resource costs that are carried by facilities even in the event that the direct costs involved in furnishing a service in the office and facility settings are comparable.

We stated our belief that our proposal provides a reliable means for Medicare to set upper payment limits for office-based procedures based on relatively more reliable cost information available for the same procedures when furnished in a facility setting where the cost structure would be expected to be somewhat, if not significantly, higher than the office setting. We

believe that the current basis for estimating the resource costs involved in furnishing a PFS service is significantly encumbered by our current inability to obtain accurate information regarding supply and equipment prices, as well as procedure time assumptions. We believe that our proposed policy would mitigate the negative impact of these difficulties on both the appropriate relativity of PFS services and overall Medicare spending. A wide range of stakeholders and public commenters have pointed to the nonfacility setting as the most cost-effective location for services. Given the significantly higher cost structure of facilities (as discussed above) we believe that this presumption is accurate. In its March 2012 report to Congress, MedPAC recommended that Medicare should seek to pay similar amounts for similar services across payment settings, taking into account differences in the definitions of services and patient severity. (MedPAC March 2012 Report to Congress, page 46) We believe that the proposed change to our PFS PE methodology would more appropriately reflect resource costs in the nonfacility setting.

Comment: One commenter representing primary care physicians supported the proposal and indicated a belief that the proposed policy would help to correct misvaluation between primary care services and the services affected by the policy. Another commenter supported the policy as an interim step until an expedited review of the services could be conducted. Other commenters, while not supporting the proposal due to the financial impact on certain services, stated that hospitals and ASCs do typically incur higher overhead costs in delivering services than physician offices.

The overwhelmingly majority of commenters objected to the proposed policy. Several commenters believed the services impacted by the policy were potentially misvalued, but still opposed our policy. Many commenters questioned whether facilities' costs for providing all

services are necessarily higher than the costs of physicians or other practitioners. Commenters stated that the resources required to furnish services in nonfacility physician settings cannot be accurately measured using the OPPS methodology and that our proposal would result in rank order anomalies. Commenters indicated that it was inappropriate to base PFS payment on OPPS payment since a single APC contains multiple services that can involve a wide a range of costs that are averaged under the OPPS methodology. Many commenters also stated that since OPPS payment rates rely on the accuracy of APC payments, developed through hospitals accurately allocating their costs and charges to particular departments/APCs. These commenters stated that hospitals may have little incentive to accurately allocate their costs and charges to particular departments/APCs since they typically provide a broad range of services and therefore have the ability to make up for losses on one service with profits on another. The argument is that this ability makes the precise pricing of individual services less important in the OPPS system than it is in the physician setting. Also, the argument is that if physicians are going to be paid based upon the OPPS system it should be for all services so that like the hospitals they benefit from those overpaid in the hospital. Many commenters also questioned CMS' authority to use payment rates from other Medicare payment methodologies to cap PFS rates since they asserted the policy violated the statutory requirement that the PFS PE relative values be based on the resources used in furnishing the service. Some commenters also cited the financial impact of our proposed policy on the PFS rates as a further reason that the policy was inappropriate.

For all of these reasons, these commenters recommended that we not adopt the proposed policy. Many of these commenters also suggested modifications to the policy if CMS did decide to move forward. Commenters suggested that since the ASC rates reflect the OPPS relative weights to determine payment rates under the ASC payment system, and are not based on cost

information collected from ASCs, the ASC rates should not be used in the proposed policy.

Commenters also stated a strong preference to use prospective year OPPS rates instead of current year OPPS rates as the point of comparison to prospective year PFS rates. The CY 2014 OPPS proposed rule proposed significant packaging that raised payment for many APCs, and therefore, raised the associated PFS cap rate.

Some commenters stated that they believed that CMS does not have authority to use any conversion factor in the policy other than the one calculated under existing law for CY 2014.

Commenters stated that the low-volume threshold (a minimum of 5 percent in the hospital outpatient setting) was proposed with insufficient rationale and recommended either a 50 percent threshold or an absolute volume threshold. Commenters also argued that there should be an ASC low-volume threshold for using ASC rates.

Commenters urged CMS to establish a means for stakeholders to demonstrate the validity of office costs relative to OPPS payments prior to implementing a cap for any particular code.

Commenters also suggested that the AMA RUC should examine each code prior to the implementation of the policy for that code.

Commenters suggested excluding codes recently revalued, such as certain surgical pathology codes, from the cap as their resource inputs and costs are more accurate than those less recently revalued.

Commenters suggested that CMS should make the cap more transparent by identifying all affected codes and displaying the data used in establishing the capped values.

Several commenters suggested using the individual OPPS HCPCS code costs that are used to calculate the APC payment, rather than the APC payment rate itself, as a way of avoiding the problems caused by the averaging that goes on in calculating the APC rates. These

commenters argued that individual code costs are a more appropriate comparison than APC payment rates.

Response: As we stated in the proposed rule, when services are furnished in the facility setting, such as an HOPD or ASC, the total Medicare payment (made to the facility and the professional combined) typically exceeds the Medicare payment made for the same service when furnished in the physician office or other nonfacility setting. We continue to believe that this payment difference generally reflects the greater costs that facilities incur compared to those incurred by practitioners furnishing services in offices and other non-facility settings. We also continue to believe that if the total Medicare payment when a service is furnished in the physician office setting exceeds the total Medicare payment when a service is furnished in an HOPD or an ASC, this is generally not the result of appropriate payment differentials between the services furnished in different settings. Rather, we continue to believe that it is primarily due to anomalies in the data we use under the PFS and in the application of our resource-based PE methodology to the particular services.

We greatly appreciate all of the comments that we received on our proposal. Given the many thoughtful and detailed technical comments that we received, we are not finalizing our proposed policy in this final rule with comment period. We will consider more fully all the comments received, including those suggesting technical improvements to our proposed methodology. After further consideration of the comments, we expect to develop a revised proposal for using OPPS and ASC rates in developing PE RVUs which we will propose through future notice and comment rulemaking.

At this time, we do not believe that our standard process for evaluating potentially misvalued codes, including the use of the AMA RUC is an effective means of addressing these

codes. As we stated in the proposed rule, we do not believe that the direct practice expense information we currently use to value these codes is accurate or reflects typical resource costs. We have addressed these issues extensively in previous rulemaking (for example, 75 FR 73252) and again in section II.B.4. of this final rule with comment period. We believe the current review process for direct PE inputs only accommodates incomplete, small sample, and potentially biased or inaccurate resource input costs that may distort the resources used to develop nonfacility PE RVUs used in calculating PFS payment rates for individual services.

3. Ultrasound Equipment Recommendations

In the CY 2012 PFS proposed rule (76 FR 42796), we asked the AMA RUC to review the ultrasound equipment described in the direct PE input database. We specifically asked for review of the ultrasound equipment items described in the direct PE input database and whether the ultrasound equipment listed for specific procedure codes is clinically necessary.

In response, the AMA RUC recommended creating several new equipment inputs in addition to the revision of current equipment inputs for ultrasound services. The AMA RUC also forwarded pricing information for new and existing equipment items from certain medical specialty societies that represent the practitioners who furnish these services. In the following paragraphs, we summarize the AMA RUC recommendations, address our review of the provided information, and describe a series of changes we proposed to the direct PE inputs used in developing PE RVUs for these services for CY 2014.

(1) Equipment Rooms

The AMA RUC made a series of recommendations regarding the ultrasound equipment items included in direct PE input equipment packages called "rooms." Specifically, the AMA RUC recommended adding several new equipment items to the equipment packages called

"room, ultrasound, general" (EL015) and "room, ultrasound, vascular" (EL016). The AMA RUC also recommended creating a similar direct PE input equipment package called "room, ultrasound, cardiovascular." In considering these recommendations, we identified a series of new concerns regarding the makeup of these equipment packages and because there are several different ways to handle these concerns. In the CY 2014 PFS proposed rule we sought public comment from stakeholders prior to proposing to implement any of these recommended changes through future rulemaking.

We noted that the existing "rooms" for ultrasound technology include a greater number of individual items than the "rooms" for other kinds of procedures. For example, the equipment package for the "room, basic radiology" (EL012) contains only two items: an x-ray machine and a camera. Ordinarily under the PFS, direct PE input packages for "rooms" include only equipment items that are typically used in furnishing every service in that room. When equipment items beyond those included in a "room" are typically used in furnishing a particular procedure, the additional equipment items for that procedure are separately reflected in the direct PE input database in addition to the "room" rather than being included in the room. When handled in this way, the room includes only those inputs that are common to all services furnished in that room type, and thus the direct PE inputs are appropriate for the typical case of each particular service. When additional equipment items are involved in furnishing a particular service, they are included as an individual PE input only for that particular service.

In contrast, the equipment items currently included in the "room, ultrasound, general" are: the ultrasound system, five different transducers, two probe starter kits, two printers, a table, and various other items. In the proposed rule, we stated that we do not believe that it is likely that all of these items would be typically used in furnishing each service. For example, we do

not believe that the typical ultrasound study would require the use of five different ultrasound transducers. However, the costs of all of these items are incorporated into the resource inputs for every service for which the ultrasound room is a direct PE input, regardless of whether each of those items is typically used in furnishing the particular service. This increases the resource cost for every service that uses the room regardless of whether or not each of the individual items is typically used in furnishing a particular procedure.

Instead of proposing to incorporate the AMA RUC's recommendation to add more equipment items to these ultrasound equipment "room" packages, we stated our intention to continue to consider the appropriateness of the full number of items in the ultrasound "rooms" in the context of maintaining appropriate relativity with other services across the PFS. We sought comment from stakeholders, including the AMA RUC, on the items included in the ultrasound rooms, especially as compared to the items included in other equipment "rooms." We stated that we thought that it would be appropriate to consider these comments in future rulemaking instead of proposing to alter the existing "rooms" just for ultrasound equipment items for CY 2014. Specifically we sought comment on whether equipment packages called "rooms" should include all of the items that might be included in an actual room, just the items typically used for every service in such a room, or all of the items typically used in typical services furnished in the room. We stated that we believed that it would be most appropriate to propose changes to the "room, ultrasound, general" (EL015) and "room, ultrasound, vascular" (EL016) in the context of considering comments on this broader issue. We also stated that we believed that consideration of the broader issue will help determine whether it would be appropriate to create a "room, ultrasound, cardiovascular," and if so, what items would be included in this equipment package.

Comment: Several commenters, including the AMA RUC, suggested that equipment

room packages should include all items that are typically in the room and cannot be used for another patient, in order to furnish all typical services performed in that room. In its comment letter, the AMA RUC urged CMS to adopt its previous recommendations and pointed out that CMS has previously stated that equipment time is comprised of any time that clinical labor is using the piece of equipment, plus any additional time the piece of equipment is not available for use with another patient due to its use during the procedure in question. Therefore, any time a piece of equipment is not available for use with another patient, the equipment should be allocated minutes. The AMA RUC also pointed out, as an example, that the equipment item called "otoscope-ophthalmoscope (wall unit)" (EQ189) is a standard equipment input for all E/M codes even though it may not be typically used for each E/M service. Therefore, items included in the room but not necessarily typically used in furnishing particular services should be included as equipment minutes for all codes that typically use the room.

Response: We appreciate the responses of the AMA RUC and others regarding our questions regarding equipment packages. We remain concerned about the appropriate estimate of resources regarding equipment items, especially those in room packages. We note that in our previous statements regarding allocation of equipment minutes, we have articulated that equipment minutes should be allocated to particular items when those items are unavailable for use with another patient "due to its use during the procedure in question." Based on the recommended equipment room packages, we are concerned that this definition may not apply consistently in the direct PE input database. While we understand the example of the "otoscope-ophthalmoscope (wall unit)" (EQ189) for E/M services, we believe that there may be other medical equipment items in a typical evaluation room in addition to the otoscope-ophthalmoscope (wall unit) and an exam table.

These comments reinforce our belief that, for the sake of relativity and accuracy, changes to particular equipment room packages should be made in the context of a broader examination of all equipment packages, as well as assumed equipment utilization rates for these packages.

In addition to the concerns regarding the contents of the ultrasound "room" packages, we also expressed concerned about the pricing information submitted through the AMA RUC to support its recommendation to add equipment to the ultrasound room packages. The highestprice item used in pricing the existing equipment input called "room, ultrasound, general" (EL015), is a "GE Logic 9 ultrasound system," currently priced at \$220,000. As part of the AMA RUC recommendation described in the proposal, a medical specialty society recommended increasing the price of that item to \$314,500. However, that recommendation did not include documentation to support the pricing level, such as a copy of a paid invoice for the equipment. Furthermore, the recommended price conflicts with certain publicly available information. For example, the Milwaukee Sentinel-Journal reported in a February 9, 2013 article that the price for GE ultrasound equipment ranges from "\$7,900 for a hand-held ultrasound to \$200,000 for its most advanced model." The same article points to an item called the "Logiq E9" as the ultrasound machine most used by radiologists and priced from \$150,000 to \$200,000. http://www.jsonline.com/business/ge-sees-strong-future-with-its-ultrasound-business-uj8mn79-190533061.html

In the proposed rule, we noted that we were unsure how to best reconcile the information disclosed by the manufacturer to the press and the prices submitted by the medical specialty society for use in updating the direct PE input prices. We believe discrepancies, such as these, exemplify the potential problem with updating prices for particular items based solely on price quotes or information other than copies of paid invoices. However, copies of paid invoices must

also be evaluated carefully. The information presented in the article regarding the price for hand-held ultrasound devices raises questions about the adequacy of paid invoices, too, in determining appropriate input costs. The direct PE input described in the database as "ultrasound unit, portable" (EQ250) is currently priced at \$29,999 based on a submitted invoice, while the article cites that GE sells a portable unit for as low as \$7,900. We sought comment on the appropriate price to use as the typical for portable ultrasound units.

<u>Comment</u>: We received several comments regarding the appropriate means to price the direct PE inputs. The AMA RUC and several specialty expressed concern that it is difficult for medical specialty societies to obtain paid invoices for equipment and supplies, especially for large equipment items that are bought infrequently.

Several medical specialty societies suggested that their members are often uncomfortable sending invoices for expensive items since the prices are often proprietary and even though identifying information is redacted, the invoices are sometimes distributed to all AMA RUC meeting participants and available to the public once submitted to CMS. The specialty society suggested that certain stakeholders in the marketplace are often able to identify the individual practice submitting the invoice through this process and that such public revelation of the propriety pricing information may have major implications for the provider in future price negotiations and service lines in local markets for any practitioner volunteering such information.

The AMA RUC expressed a shared concern with CMS about pricing information submitted as supporting documentation for the ultrasound room packages and stated that it will work with medical specialty societies to provide paid invoices as soon as possible. The AMA RUC also noted that it will work with the specialties to ensure that paid invoices, rather than

quotes, are submitted to CMS. Several commenters objected to CMS' suggestion that a newspaper article might more accurately reflect typical resource costs than an invoice.

Response: We appreciate the response of the AMA RUC to these concerns. We also appreciate that in many cases the staff of medical specialty societies may have difficulty obtaining paid invoices. However, we believe the difficulty in obtaining invoices due to market sensitivity does not negate or lessen the critical importance of using accurate pricing information in establishing direct PE inputs. We believe it is likely that the pricing information would be less market sensitive if the information served to confirm the assumptions we already display in the direct PE input database. We appreciate the concerns shared by the AMA RUC's and we continue to seek the best means to identify typical resource costs associated with disposable supplies and medical equipment. While we believe that a copy of a paid invoice is the minimal amount of necessary information for pricing a disposable supply or medical equipment input, we reiterate our concerns that, even when proffered, a sole paid invoice is not necessarily the optimal source for identifying typical resource costs. We agree with commenters that information a manufacturer provides the news media is not necessarily accurate. However, when such information stands in stark contrast to single invoices, we believe it is imperative to attempt to reconcile that information to identify the best available information regarding the typical cost. We will continue to consider the perspectives offered by these commenters in developing future proposals regarding the pricing of individual items and equipment packages.

(2) New Equipment Inputs and Price Updates

<u>Ultrasound Unit, portable, breast procedures.</u> The AMA RUC recommended that a new direct PE input, "ultrasound unit, portable, breast procedures," be created for breast procedures that are performed in a surgeon's office and where ultrasound imaging is included in the code

descriptor. These services are described by CPT codes 19105 (Ablation, cryosurgical, of fibroadenoma, including ultrasound guidance, each fibroadenoma), 19296 (Placement of radiotherapy afterloading expandable catheter (single or multichannel) into the breast for interstitial radioelement application following partial mastectomy, includes imaging guidance; on date separate from partial mastectomy), and 19298 (Placement of radiotherapy afterloading brachytherapy catheters (multiple tube and button type) into the breast for interstitial radioelement application following (at the time of or subsequent to) partial mastectomy, includes imaging guidance). As we noted in the proposed rule, we are creating this input. The pricing information submitted for this item is a paid invoice and two price quotes. As we have previously stated, we believe that copies of paid invoices are more likely to reflect actual resource costs associated with equipment and supply items than quotes or other information. Therefore, we proposed a price of \$33,930, which reflects the price displayed on the submitted copy of the paid invoice. We are not using the quotes as we do not believe that quotes provide reliable information about the prices that are actually paid for medical equipment. We did not receive any additional information regarding the price for this equipment item. Therefore the CY 2014 direct PE input database reflects the price as proposed.

Endoscopic Ultrasound Processor. The AMA RUC recommended creating a new direct PE input called "endoscopic ultrasound processor," for use in furnishing the service described by CPT code 31620 (Endobronchial ultrasound (EBUS) during bronchoscopic diagnostic or therapeutic intervention(s) (List separately in addition to code for primary procedure[s])). We created this equipment item to use as an input in the direct PE input database. The price associated with the "endoscopic ultrasound processor" is \$59,925, which reflects the price documented on the copy of the paid invoice submitted with the recommendation. We did not

receive any additional information regarding the price for this equipment item. Therefore the CY 2014 direct PE input database reflects the price as proposed.

Bronchofibervideoscope. The AMA RUC recommended creating a new direct PE input called "Bronchofibervideoscope," for use in furnishing the service described by CPT code 31620 (Endobronchial ultrasound (EBUS) during bronchoscopic diagnostic or therapeutic intervention(s) (List separately in addition to code for primary procedure[s])). We created this new equipment item to use as an input in the direct PE input database. However, this item had no price associated with it in the proposed direct PE input database because we did not receive any information that would allow us to price the item accurately. Consequently, we sought copies of paid invoices for this equipment item in the CY 2014 proposed rule so that we could price the item accurately in the future.

<u>Comment:</u> One commenter reported that the current sales price for the bronchofibervideoscope ranges from \$30,000 - \$50,000. The commenter provided an invoice for the equipment that reflected a price of \$35,200.

<u>Response:</u> Based on the submission of the invoice information, we have updated the direct PE input database to reflect a price of \$35,200 for the Bronchofibervideoscope (ER093).

Endoscope, ultrasound probe, drive (ES015). The AMA RUC forwarded pricing information to us regarding the existing input called "endoscope, ultrasound probe, drive" (ES015), including a copy of a paid invoice. Based on this information, we proposed to change the price associated with ES015 to \$13,256.25, which reflects the price documented on the submitted copy of the paid invoice. We did not receive any additional information regarding the price for this equipment item. Therefore, we the CY 2014 direct PE input database reflects the price as proposed.

(2) Ultrasound Equipment Input Recommendations for Particular Services

The AMA RUC made recommendations regarding the typical ultrasound items used in furnishing particular services. In general, the AMA RUC recommended that the existing equipment items accurately described the typical equipment used in furnishing particular services. However, for some CPT codes the AMA RUC recommended changing the associated equipment inputs that appear in the direct PE input database. Based on our review of these recommendations, we generally agreed with the AMA RUC regarding these recommended changes, and the recommended changes are reflected in the direct PE input database. Table 10 displays the codes with changes to ultrasound equipment. However, for certain codes we did not agree with the recommendations of the AMA RUC. The following paragraphs address the changes we proposed that differ from the recommendations of the AMA RUC.

For a series of cardiovascular services that include ultrasound technology, the AMA RUC recommended removing certain equipment items and replacing those items with a new item called "room, ultrasound, cardiovascular." As we described in the preceding paragraphs, we did not propose to create the "room, ultrasound, cardiovascular" and therefore did not propose to add this "room" as an input for these services. However, we noted that the newly recommended equipment package incorporates many of the same kinds of items as the currently existing "room, ultrasound, vascular" (EL016). We agreed with the AMA RUC's suggestion that the existing equipment inputs for the relevant services listed in Table 10 do not reflect typical resource costs of furnishing the services. We believed that, pending our further consideration of the ultrasound "room" equipment packages, it would be appropriate to use the existing "room, ultrasound, vascular" (EL016) as a proxy for resource costs for these services.

Comment: Several commenters urged CMS to accept the AMA RUC's

recommendations. Most of these commenters suggested that if CMS were not to accept the AMA RUC's recommendation to create the new "cardiovascular ultrasound room" for CY 2014, then the inputs for the existing "room, ultrasound, vascular" (EL016) should be used. A few commenters representing some of the practitioners who furnish some of these services objected to the change in equipment inputs based on their assertion that the members of their specialty societies typically use more resource intensive equipment than reflected in the AMA RUC recommendations. One of these commenters suggested that the CPT codes for fetal echocardiography (CPT codes 76825, 76826, 78627, and 78628) previously included the same equipment items as the other echocardiography codes with equipment updates. This commenter suggested that the equipment for these codes should be updated to correspond with the equipment for other, similar services.

Response: As we noted in the proposed rule, we believe that the issue of equipment room packages should be addressed in future rulemaking. Based on these comments, we are finalizing the use of the existing "room, ultrasound, vascular" (EL016) as a proxy for resource costs for these services pending future consideration of equipment room packages. We note that the AMA RUC based its recommendation on information obtained from the medical specialty societies that represent the specialty of the practitioners who furnish the majority of allowed services for each of these codes using recent Medicare claims data. We examined the comments we received objecting to the finalization of the AMA RUC-recommended equipment recommendations and, in each case, confirmed that the commenters did not represent the practitioners who typically furnish each service according to the Medicare claims data. In the case of the fetal echocardiography codes, we agree with the commenter's suggestion that the equipment for these codes should correspond with the equipment for the similar services,

especially since the AMA RUC recommended replacing these items for all other codes in the direct PE inputs database. Based on that review, we remain confident that our proposal is appropriate and we are finalizing the changes in the ultrasound equipment items as proposed, with the exception of updating the equipment items for fetal echocardiography to be consistent with other echocardiography services. These changes are displayed in Table 10 and incorporated in the CY 2014 direct PE input database.

In the case of CPT code 76942 (Ultrasonic guidance for needle placement (for example, biopsy, aspiration, injection, localization device), imaging supervision and interpretation), we agreed with the AMA RUC's recommendation to replace the current equipment input of the "room, ultrasound, general" (EL015) with "ultrasound unit, portable" (EQ250). We note that this service is typically reported with other codes that describe the needle placement procedures and that the recommended change in equipment from a room to a portable device reflects a change in the typical kinds of procedures reported with this image guidance service. Given this change, we believe that it is appropriate to reconsider the procedure time assumption currently used in establishing the direct PE inputs for this code, which is 45 minutes. We reviewed the services reported with CPT code 76942 to identify the most common procedures furnished with this image guidance. The code most frequently reported with CPT code 76942 is CPT 20610 (Arthrocentesis, aspiration and/or injection; major joint or bursa (for example, shoulder, hip, knee joint, subacromial bursa). The assumed procedure time for this service is five minutes. The procedure time assumptions for the vast majority of other procedures frequently reported with CPT code 76942 range from 5 to 20 minutes. Therefore, in addition to proposing the recommended change in equipment inputs associated with the code, we proposed to change the procedure time assumption used in establishing direct PE inputs for the service from 45 to 10

minutes, based on our analysis of 30 needle placement procedures most frequently reported with CPT code 76942. We noted that this reduced the clinical labor and equipment minutes associated with the code from 58 to 23 minutes.

Comment: Several commenters noted that the AMA RUC is planning to conduct surveys and review the assumptions regarding the code and that CMS will be in a better position to make more accurate determinations if it waits for that data from the AMA RUC. One commenter stated that CMS should not make a change in the direct PE input database based on information in the Medicare claims data without input from the medical specialty societies whose members furnish and report the ultrasound guidance as described with CPT code 76942 and that a recommendation from the AMA RUC may provide better data than the information contained on Medicare claims.

Response: We appreciate the partnership of the AMA RUC in the misvalued code initiative, but as a general principle, we do not believe that we should refrain from making appropriate changes to code values solely because the AMA RUC is planning to review a service in the future. In some cases, we believe that we should examine claims information and other sources of data and make proposals regarding the appropriate inputs used to develop the amount Medicare pays for PFS services. We believe that notice and comment rulemaking itself provides a means for the public, including medical specialty societies and the AMA RUC, to respond substantively to proposed changes in resource inputs for particular services. Furthermore, in cases like this one, we do not believe that the information reflected in the Medicare claims data is subjective or open to differing interpretations.

<u>Comment:</u> Several commenters, including the AMA RUC, pointed out that CPT code 76942 includes supervision and interpretation, which represents both time and work that is

separate from the surgical code and that the additional time included in the direct PE inputs may reflect time in addition to the base procedure.

Response: We appreciate the response of the AMA RUC and others in pointing out concerns with our assumptions. We note that the proposed clinical labor service period of 23 minutes includes the 10 minutes of intra-service time in addition to 2 minutes for preparing the room, equipment, and supplies, 3 minutes for preparing and positioning the patient, 3 minutes for cleaning the room, and 5 minutes for processing images, completing data sheet, and presenting images and data to the interpreting physician. We did not receive information from any commenters suggesting that the time allocated for these tasks was inadequate. Therefore, we are finalizing our adjustment to the clinical labor minutes associated with this code, as proposed.

TABLE 10: Codes with Changes to Ultrasound Equipment for CY 2014

CPT Code	Descriptor	CY 2013 CMS Equipment Code	CY 2013 Equipment Description	CY 2014 Equipment CMS Code	CY 2014 Equipment Description
19105	Cryosurg ablate fa each	EQ250	ultrasound unit, portable	NEW	ultrasound unit, portable, breast procedures
19296	Place po breast cath for rad	EL015	room, ultrasound, general	NEW	ultrasound unit, portable, breast procedures
19298	Place breast rad tube/caths	EL015	room, ultrasound, general	NEW	ultrasound unit, portable, breast procedures
	Endobronchial		n/a	NEW	Bronchofibervideoscope
31620	us add-on	n/a		NEW	Endoscopic ultrasound processor
52649	Prostate laser enucleation	EQ255	ultrasound, noninvasive bladder scanner w-cart	EQ250	ultrasound unit, portable
76376	3d render w/o postprocess	EL015	room, ultrasound, general	Remove input	
76775	Us exam abdo back wall lim	EL015	room, ultrasound, general	EQ250	ultrasound unit, portable
76820	Umbilical artery echo	EQ249	ultrasound color doppler, transducers and vaginal probe	EL015	room, ultrasound, general

CPT Code	Descriptor	CY 2013 CMS Equipment Code	CY 2013 Equipment Description	CY 2014 Equipment CMS Code	CY 2014 Equipment Description
76825	Echo exam of fetal heart	EQ254	ultrasound, echocardiography w-4 transducers (Sequoia C256)	EL016	room, ultrasound, vascular
		EQ252	ultrasound, echocardiography analyzer software (ProSolv)		
76826	Echo exam of fetal heart	EQ254	ultrasound, echocardiography w-4 transducers (Sequoia C256)	EL016	room, ultrasound, vascular
		EQ252	ultrasound, echocardiography analyzer software (ProSolv)		
76827	Echo exam of fetal heart	EQ254	ultrasound, echocardiography w-4 transducers (Sequoia C256)	EL016	room, ultrasound, vascular
76828	Echo exam of fetal heart	EQ254	ultrasound, echocardiography w-4 transducers (Sequoia C256)	EL016	room, ultrasound, vascular
76857	Us exam pelvic limited	EL015	room, ultrasound, general	EQ250	ultrasound unit, portable
76870	Us exam scrotum	EL015	room, ultrasound, general	EQ250	ultrasound unit, portable
76872	Us transrectal	EL015	room, ultrasound, general	EQ250	ultrasound unit, portable
76942	Echo guide for biopsy	EL015	room, ultrasound, general	EQ250	ultrasound unit, portable
93303	Echo guide for biopsy	EQ253	ultrasound, echocardiography digital acquisition (Novo Microsonics, TomTec)	EL016	room, ultrasound, vascular
		EQ254	ultrasound, echocardiography w-4 transducers (Sequoia C256)		

CPT Code	Descriptor	CY 2013 CMS Equipment Code	CY 2013 Equipment Description	CY 2014 Equipment CMS Code	CY 2014 Equipment Description	
		EQ252	ultrasound, echocardiography analyzer software (ProSolv)			
	Echo transthoracic	EQ252	ultrasound, echocardiography analyzer software (ProSolv)	EL016	room, ultrasound, vascular	
93304		EQ253	ultrasound, echocardiography digital acquisition (Novo Microsonics, TomTec)			
		EQ254	ultrasound, echocardiography w-4 transducers (Sequoia C256)			
93306	Tte w/doppler complete	EQ253	ultrasound, echocardiography digital acquisition (Novo Microsonics, TomTec)			
			EQ254	ultrasound, echocardiography w-4 transducers (Sequoia C256)	EL016	room, ultrasound, vascular
		EQ252	EQ252 ultrasound, echocardiography analyzer software (ProSolv)			
93307	Tte w/o doppler complete	EQ252	ultrasound, echocardiography analyzer software (ProSolv)	EL016	room, ultrasound, vascular	
			ultrasound, echocardiography digital acquisition (Novo Microsonics, TomTec)			
		EQ254	ultrasound, echocardiography w-4 transducers (Sequoia C256)			
93308	Tte f-up or lmtd	EQ252	ultrasound, echocardiography analyzer software (ProSolv)	EL016	room, ultrasound, vascular	

CPT Code	Descriptor	CY 2013 CMS Equipment Code	CY 2013 Equipment Description	CY 2014 Equipment CMS Code	CY 2014 Equipment Description
		EQ253	ultrasound, echocardiography digital acquisition (Novo Microsonics, TomTec)		
		EQ254	ultrasound, echocardiography w-4 transducers (Sequoia C256)		
		EQ253	ultrasound, echocardiography digital acquisition (Novo Microsonics, TomTec)		
93312	Echo transesophageal	EQ252	ultrasound, echocardiography analyzer software (ProSolv)	EL016	room, ultrasound, vascular
		EQ256	ultrasound, transducer (TEE Omniplane II)		
		EQ254	ultrasound, echocardiography w-4 transducers (Sequoia C256)		
		EQ254	ultrasound, echocardiography w-4 transducers (Sequoia C256)		
		EQ256	ultrasound, transducer (TEE Omniplane II)		
93314	Echo transesophageal	EQ252	ultrasound, echocardiography analyzer software (ProSolv)	EL016	room, ultrasound, vascular
		EQ253	ultrasound, echocardiography digital acquisition (Novo Microsonics, TomTec)		
93320	Doppler echo exam heart	EQ252	ultrasound, echocardiography analyzer software (ProSolv)	EL016	room, ultrasound, vascular
		EQ253	ultrasound, echocardiography digital acquisition (Novo Microsonics, TomTec)		

CPT Code	Descriptor	CY 2013 CMS Equipment Code	CY 2013 Equipment Description	CY 2014 Equipment CMS Code	CY 2014 Equipment Description	
		EQ254	ultrasound, echocardiography w-4 transducers (Sequoia C256)			
93321	Doppler echo exam heart	EQ252	ultrasound, echocardiography analyzer software (ProSolv)	EL016	room, ultrasound, vascular	
73321		EQ254	ultrasound, echocardiography w-4 transducers (Sequoia C256)			
		EQ252	ultrasound, echocardiography analyzer software (ProSolv)			
93325	Doppler color flow add-on		EQ253	ultrasound, echocardiography digital acquisition (Novo Microsonics, TomTec)	EL016	room, ultrasound, vascular
			EQ254	ultrasound, echocardiography w-4 transducers (Sequoia C256)		
	Stress tte only	EQ252	ultrasound, echocardiography analyzer software (ProSolv)		room, ultrasound, vascular	
93350		EQ253	ultrasound, echocardiography digital acquisition (Novo Microsonics, TomTec)	EL016		
		EQ254	ultrasound, echocardiography w-4 transducers (Sequoia C256)			
93351	Stress tte complete	EQ254	ultrasound, echocardiography w-4 transducers (Sequoia C256)	EL016	room, ultrasound, vascular	
93980	Penile vascular study	EL015	room, ultrasound, general	EQ249	ultrasound color doppler, transducers and vaginal probe	
93981	Penile vascular study	EL015	room, ultrasound, general	EQ249	ultrasound color doppler, transducers and vaginal probe	

B. Misvalued Services

1. Valuing Services Under the PFS

Section 1848(c) of the Act requires the Secretary to determine relative values for physicians' services based on three components: work, PE, and malpractice. Section 1848(c)(1)(A) of the Act defines the work component to include "the portion of the resources used in furnishing the service that reflects physician time and intensity in furnishing the service." In addition, section 1848(c)(2)(C)(i) of the Act specifies that "the Secretary shall determine a number of work relative value units (RVUs) for the service based on the relative resources incorporating physician time and intensity required in furnishing the service." Section 1848(c)(1)(B) of the Act defines the PE component as "the portion of the resources used in furnishing the service that reflects the general categories of expenses (such as office rent and wages of personnel, but excluding malpractice expenses) comprising practice expenses." (See section I.B.1.b. for more detail on the development of the PE component.) Section 1848(c)(1)(C) of the Act defines the malpractice component as "the portion of the resources used in furnishing the service that reflects malpractice expenses in furnishing the service." Sections 1848 (c)(2)(C)(ii) and (iii) of the Act specify that PE and malpractice RVUs shall be determined based on the relative PE/malpractice resources involved in furnishing the service.

Section 1848(c)(2)(B) of the Act directs the Secretary to conduct a periodic review, not less often than every 5 years, of the RVUs established under the PFS. Section 3134(a) of the Affordable Care Act added a new section 1848(c)(2)(K) to the Act, which requires the Secretary to periodically identify potentially misvalued services using certain criteria and to review and make appropriate adjustments to the relative values for those services. Section 3134(a) of the Affordable Care Act also added a new section 1848(c)(2)(L) to the Act, which requires the Secretary to develop a process to validate the RVUs of certain potentially misvalued codes under the PFS, identified using the same criteria used to identify potentially misvalued codes, and to make appropriate adjustments.

As discussed in section II.B.1. of this final rule with comment period, each year we develop and propose appropriate adjustments to the RVUs, taking into account the recommendations provided by the

American Medical Association/Specialty Society Relative Value Scale Update Committee (AMA RUC), the Medicare Payment Advisory Commission (MedPAC), and others. For many years, the AMA RUC has provided us with recommendations on the appropriate relative values for new, revised, and potentially misvalued PFS services. We review these recommendations on a code-by-code basis and consider these recommendations in conjunction with analyses of other data, such as claims data, to inform the decisionmaking process as authorized by the law. We may also consider analyses of physician time, work RVUs, or direct PE inputs using other data sources, such as Department of Veteran Affairs (VA), National Surgical Quality Improvement Program (NSQIP), the Society for Thoracic Surgeons (STS) National Database, and the Physician Quality Reporting System (PQRS) databases. In addition to considering the most recently available data, we also assess the results of physician surveys and specialty recommendations submitted to us by the AMA RUC. We conduct a clinical review to assess the appropriate RVUs in the context of contemporary medical practice. We note that section 1848(c)(2)(A)(ii) of the Act authorizes the use of extrapolation and other techniques to determine the RVUs for physicians' services for which specific data are not available in addition to taking into account the results of consultations with organizations representing physicians. In accordance with section 1848(c) of the Act, we determine appropriate adjustments to the RVUs, explain the basis of these adjustments, and respond to public comments in the PFS proposed and final rules.

2. Identifying, Reviewing, and Validating the RVUs of Potentially Misvalued Services

a. Background

In its March 2006 Report to the Congress, MedPAC noted that "misvalued services can distort the price signals for physicians' services as well as for other health care services that physicians order, such as hospital services." In that same report MedPAC postulated that physicians' services under the PFS can become misvalued over time. MedPAC stated, "when a new service is added to the physician fee schedule, it may be assigned a relatively high value because of the time, technical skill, and psychological stress that are often required to furnish that service. Over time, the work required for certain services would be expected to decline as physicians become more familiar with the service and more efficient in

furnishing it." We believe services can also become overvalued when PEs decline. This can happen when the costs of equipment and supplies fall, or when equipment is used more frequently than is estimated in the PE methodology, reducing its cost per use. Likewise, services can become undervalued when physician work increases or PEs rise. In the ensuing years since MedPAC's 2006 report, additional groups of potentially misvalued services have been identified by the Congress, CMS, MedPAC, the AMA RUC, and other stakeholders.

In recent years, CMS and the AMA RUC have taken increasingly significant steps to identify and address potentially misvalued codes. As MedPAC noted in its March 2009 Report to Congress, in the intervening years since MedPAC made the initial recommendations, "CMS and the AMA RUC have taken several steps to improve the review process." Most recently, section 1848(c)(2)(K)(ii) of the Act (as added by section 3134(a) of the Affordable Care Act) directed the Secretary to specifically examine, as determined appropriate, potentially misvalued services in the following seven categories:

- Codes and families of codes for which there has been the fastest growth;
- Codes and families of codes that have experienced substantial changes in PEs;
- Codes that are recently established for new technologies or services;
- Multiple codes that are frequently billed in conjunction with furnishing a single service;
- Codes with low relative values, particularly those that are often billed multiple times for a single treatment;
- Codes which have not been subject to review since the implementation of the RBRVS (the socalled 'Harvard-valued codes'); and
 - Other codes determined to be appropriate by the Secretary.

Section 1848(c)(2)(K)(iii) of the Act also specifies that the Secretary may use existing processes to receive recommendations on the review and appropriate adjustment of potentially misvalued services. In addition, the Secretary may conduct surveys, other data collection activities, studies, or other analyses, as the Secretary determines to be appropriate, to facilitate the review and appropriate adjustment of potentially misvalued services. This section also authorizes the use of analytic contractors to identify and

analyze potentially misvalued codes, conduct surveys or collect data, and make recommendations on the review and appropriate adjustment of potentially misvalued services. Additionally, this section provides that the Secretary may coordinate the review and adjustment of any RVU with the periodic review described in section 1848(c)(2)(B) of the Act. Finally, section 1848(c)(2)(K)(iii)(V) of the Act specifies that the Secretary may make appropriate coding revisions (including using existing processes for consideration of coding changes) that may include consolidation of individual services into bundled codes for payment under the physician fee schedule.

b. Progress in Identifying and Reviewing Potentially Misvalued Codes

To fulfill our statutory mandate, we have identified and reviewed numerous potentially misvalued codes in all seven of the categories specified in section 1848(c)(2)(K)(ii) of the Act, and we plan to continue our work examining potentially misvalued codes in these areas over the upcoming years. In the current process, we identify potentially misvalued codes for review, and request recommendations from the AMA RUC and other public commenters on revised work RVUs and direct PE inputs for those codes. The AMA RUC, through its own processes, also identifies potentially misvalued codes for review. Through our public nomination process for potentially misvalued codes established in the CY 2012 PFS final rule with comment period, other individuals and stakeholder groups submit nominations for review of potentially misvalued codes as well.

Since CY 2009, as a part of the annual potentially misvalued code review and Five-Year Review process, we have reviewed more than 1,000 potentially misvalued codes to refine work RVUs and direct PE inputs. We have adopted appropriate work RVUs and direct PE inputs for these services as a result of these reviews. A more detailed discussion of the extensive prior reviews of potentially misvalued codes is included in the CY 2012 PFS final rule with comment period (76 FR 73052 through 73055). In the CY 2012 PFS proposed rule, we proposed to identify and review potentially misvalued codes in the category of "Other codes determined to be appropriate by the Secretary," referring to a list of the highest PFS expenditure services, by specialty, that had not been recently reviewed (76 FR 73059 through 73068).

In the CY 2012 final rule with comment period, we finalized our policy to consolidate the review of physician work and PE at the same time (76 FR 73055 through 73958), and established a process for the annual public nomination of potentially misvalued services.

One of the priority categories for review of potentially misvalued codes is services that have not been subject to review since the implementation of the PFS (the so-called "Harvard-valued codes"). In the CY 2009 PFS proposed rule, we requested that the AMA RUC engage in an ongoing effort to review the remaining Harvard-valued codes, focusing first on the high-volume, low intensity codes (73 FR 38589). For the Fourth Five-Year Review (76 FR 32410), we requested that the AMA RUC review services that have not been reviewed since the original implementation of the PFS with annual utilization greater than 30,000 (Harvard-valued—Utilization > 30,000). In the CY 2013 final rule with comment period, we identified for review the potentially misvalued codes for Harvard-valued services with annual allowed charges that total at least \$10,000,000 (Harvard-valued—Allowed charges ≥\$10,000,000).

In addition to the Harvard-valued codes, in the same rule we finalized for review a list of potentially misvalued codes that have stand-alone PE (these are codes with clinical labor procedure time assumptions not connected or dependent on physician time assumptions; see 77 FR 68918 for detailed information).

c. Validating RVUs of Potentially Misvalued Codes

In addition to identifying and reviewing potentially misvalued codes, section 3134(a) of the Affordable Care Act added section 1848(c)(2)(L) of the Act, which specifies that the Secretary shall establish a formal process to validate RVUs under the PFS. The validation process may include validation of work elements (such as time, mental effort and professional judgment, technical skill and physical effort, and stress due to risk) involved with furnishing a service and may include validation of the pre-, post-, and intra-service components of work. The Secretary is directed, as part of the validation, to validate a sampling of the work RVUs of codes identified through any of the seven categories of potentially misvalued codes specified by section 1848(c)(2)(K)(ii) of the Act. Furthermore, the Secretary may conduct the validation using methods similar to those used to review potentially misvalued codes,

including conducting surveys, other data collection activities, studies, or other analyses as the Secretary determines to be appropriate to facilitate the validation of RVUs of services.

In the CY 2011 PFS proposed rule (75 FR 40068) and CY 2012 PFS proposed rule (76 FR 42790), we solicited public comments on possible approaches, methodologies, and data sources that we should consider for a validation process. A summary of the comments along with our responses are included in the CY 2011 PFS final rule with comment period (75 FR 73217) and the CY 2012 PFS final rule with comment period (73054 through 73055).

As we indicated in the CY 2014 PFS proposed rule (78 FR 43304), we have entered into two contracts with outside entities to develop validation models for RVUs. During a 2-year project, the RAND Corporation will use available data to build a validation model to predict work RVUs and the individual components of work RVUs, time and intensity. The model design will be informed by the statistical methodologies and approach used to develop the initial work RVUs and to identify potentially misvalued procedures under current CMS and AMA RUC processes. RAND will use a representative set of CMS-provided codes to test the model. RAND will consult with a technical expert panel on model design issues and the test results.

The second contract is with the Urban Institute. Given the central role of time in establishing work RVUs and the concerns that have been raised about the current time values, a key focus of the project is collecting data from several practices for selected services. The data will be used to develop time estimates. Urban Institute will use a variety of approaches to develop objective time estimates, depending on the type of service, which will be a very resource-intensive part of the project. Objective time estimates will be compared to the current time values used in the fee schedule. The project team will then convene groups of physicians from a range of specialties to review the new time data and their potential implications for work and the ratio of work to time.

The research being performed under these two contracts continues. For additional information, please visit our website (http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/RVUs-Validation-Model.pdf).

- 3. CY 2014 Identification and Review of Potentially Misvalued Services
- a. Public Nomination of Potentially Misvalued Codes

The public and stakeholders may nominate potentially misvalued codes for review by submitting the code with supporting documentation during the 60-day public comment period following the release of the annual PFS final rule with comment period under a process we finalized in the CY 2012 PFS final rule with comment period (76 FR 73058). Supporting documentation for codes nominated for the annual review of potentially misvalued codes may include the following:

- Documentation in the peer-reviewed medical literature or other reliable data that there have been changes in physician work due to one or more of the following: technique; knowledge and technology; patient population; site-of-service; length of hospital stay; and physician time.
 - An anomalous relationship between the code being proposed for review and other codes.
 - Evidence that technology has changed physician work, that is, diffusion of technology.
- Analysis of other data on time and effort measures, such as operating room logs or national and other representative databases.
- Evidence that incorrect assumptions were made in the previous valuation of the service, such as a misleading vignette, survey, or flawed crosswalk assumptions in a previous evaluation.
- Prices for certain high cost supplies or other direct PE inputs that are used to determine PE
 RVUs are inaccurate and do not reflect current information.
- Analyses of physician time, work RVU, or direct PE inputs using other data sources (for example, Department of Veteran Affairs (VA) National Surgical Quality Improvement Program (NSQIP), the Society for Thoracic Surgeons (STS) National Database, and the Physician Quality Reporting System (PQRS) databases).
- National surveys of physician time and intensity from professional and management societies and organizations, such as hospital associations.

After we receive the nominated codes during the 60-day comment period following the release of the annual PFS final rule with comment period, we evaluate the supporting documentation and assess

whether the nominated codes appear to be potentially misvalued codes appropriate for review under the annual process. In the following year's PFS proposed rule, we publish the list of nominated codes and indicate whether we are proposing each nominated code as a potentially misvalued code. We encourage the public to submit nominations for potentially misvalued codes during the comment period for this CY 2014 PFS final rule with comment period.

We did not receive any public nominations of codes for consideration as potentially misvalued codes in response to the CY 2013 final rule with comment period. As a result, we did not propose any publicly nominated potentially misvalued codes in the CY 2014 proposed rule.

- b. Potentially Misvalued Codes
- i. Contractor Medical Director Identified Potentially Misvalued Codes

We began considering additional ways to broaden participation in the process of identifying potentially misvalued codes; we solicited the input of Medicare Administrative Contractor medical directors (CMDs) in making suggestions for codes to consider proposing as potentially misvalued codes.

In the proposed rule, we noted several reasons why we believed that CMD input would be valuable in developing our proposal. As a group, CMDs represent a variety of medical specialties, which makes them a diverse group of physicians capable of providing opinions across the vast scope of services covered under the PFS. They are on the front line of administering the Medicare program, with their offices often serving as the first point of contact for practitioners with questions regarding coverage, coding and claims processing. CMDs spend a significant amount of time communicating directly with practitioners and the health care industry discussing more than just the broad aspects of the Medicare program but also engaging in and facilitating specific discussions around individual services. Through their development of evidence-based local coverage determinations (LCDs), CMDs also have experience developing policy based on research.

<u>Comment</u>: Many commenters supported our seeking input from the CMDs in developing our proposal for codes to be considered as potentially misvalued codes, while others expressed concern about using input from CMDs. Some asked for details on the process that the CMDs used to identify codes and

some questioned whether CMDs possess the specialty-related expertise to determine if a service is misvalued when that service is not generally performed by a CMD's designated specialty. In addition, several commenters believe that the identification of misvalued codes (in addition to review and revision of those codes) should be carried out through the AMA RUC process with input from the medical community. These commenters oppose any effort by CMS to unilaterally change code values.

Response: The commenters are correct in noting that CMDs do not represent all specialties. We would note that in their role as CMDs, they do work on issues involving all specialties. Moreover, their role in this process was simply to assist us in identifying codes that we could consider proposing as potentially misvalued codes. After our evaluation, we proposed them as potentially misvalued codes in the CY 2014 proposed rule and sought public comment. Thus the affected specialties and other stakeholders had the opportunity to provide us with public comments as to whether or not these codes should be evaluated as potentially misvalued. If, following our consideration of public comments, we determine that these codes are potentially misvalued, the AMA RUC and others will have further opportunity to submit information and public comment about the appropriate value of the codes before we would determine the codes are in fact misvalued and make changes to the values.

Given the importance of ensuring that codes are appropriately valued, we believe it is appropriate to call upon the experience of CMDs in developing our proposal. Accordingly, we will proceed as we proposed in the CY 2014 proposed rule to consider the codes identified by CMDs as potentially misvalued codes.

In consultation with our CMDs, the following lists of codes in Tables 11 and 12 were identified as potentially misvalued in the CY 2014 proposed rule.

TABLE 11: Codes Proposed as Potentially Misvalued Identified in Consultation with CMDs

CPT Code	Short Descriptor
17311	Mohs 1 stage h/n/hf/g
17313	Mohs 1 stage t/a/l
21800	Treatment of rib fracture
22305	Closed tx spine process fx

CPT Code	Short Descriptor
27193	Treat pelvic ring fracture
33960	External circulation assist
33961	External circulation assist, each subsequent day
47560	Laparoscopy w/cholangio
47562	Laparoscopic cholecystectomy
47563	Laparo cholecystectomy/graph
55845	Extensive prostate surgery
55866	Laparo radical prostatectomy
64566	Neuroeltrd stim post tibial
76942	Echo guide for biopsy

CPT codes 17311 (Mohs micrographic technique, including removal of all gross tumor, surgical excision of tissue specimens, mapping, color coding of specimens, microscopic examination of specimens by the surgeon, and histopathologic preparation including routine stain(s) (for example, hematoxylin and eosin, toluidine blue), head, neck, hands, feet genitalia, or any location with surgery directly involving muscle, cartilage, bone, tendon, major nerves, or vessels; first stage, up to 5 tissue blocks) and 17313 (Mohs micrographic technique, including removal of all gross tumor, surgical excision of tissue specimens, mapping, color coding of specimens, microscopic examination of specimens by the surgeon, and histpathologic preparation including routine stains(s) (for example, hematoxylin and eosin, toluidine blue), of the trunk, arms, or legs; first stage, up to 5 tissue blocks) were proposed as potentially misvalued codes because we believe that these codes may be overvalued based on CMD comments suggesting excessive utilization.

<u>Comment</u>: All commenting on CPT codes 17311 and 17313 stated that these codes were being reviewed by the AMA RUC in 2013, and two suggested that we accept the AMA RUC recommended work values (6.2 and 5.56 respectively) in the 2014 PFS final rule with comment period. One commenter asserted that these codes were not misvalued and should be removed from consideration as potentially misvalued but did not supply any information to support this view.

Response: The commenters are correct that the codes were under review by the AMA RUC. Since the publication of the proposed rule, we have received recommendations from the AMA RUC for

these codes. Rather than finalizing them as potentially misvalued codes, since we have the AMA RUC recommendations we are proposing interim final values for these codes per our usual process. (See section II.E.3.a.i.) These values are open for comment during the comment period for this final rule.

CPT codes 21800 (Closed treatment of rib fracture, uncomplicated, each), 22305 (Closed treatment of vertebral process fracture(s)) and 27193 (Closed treatment of pelvic ring fracture, dislocation, diastasis or subluxation, without manipulation) were proposed for review as potentially misvalued codes.

Comment: We received no comments on these codes.

Response: We are finalizing our proposal to review these codes as potentially misvalued codes.

CPT codes 33960 (Prolonged extracorporeal circulation for cardiopulmonary insufficiency; initial day) and 33961 (Prolonged extracorporeal circulation for cardiopulmonary insufficiency; each subsequent day) were proposed for review because the service was originally valued when it was used primarily in premature neonates; but the service is now being furnished to adults with severe influenza, pneumonia and respiratory distress syndrome. We also noted in the proposed rule that, while the code currently includes 523 minutes of total physician time with 133 minutes of intraservice time, physicians are not typically furnishing the service over that entire time interval; rather, hospital-employed pump technicians are furnishing much of the work.

Comment: We received no comments on these codes.

Response: We are finalizing our proposal to review these codes as potentially misvalued codes.

CPT codes 47560 (Laparoscopy, surgical; with guided transhepatic cholangiography, without biopsy), 47562 (Laparoscopy, surgical; cholecystectomy) and 47563 (Laparoscopy, surgical; cholecystectomy with cholangiography) were proposed as potentially misvalued because the more extensive code (CPT 47560) has lower work RVUs than the less extensive codes (CPT 47562 and CPT 47563).

<u>Comment</u>: We received a comment suggesting that these codes were not potentially misvalued and urging us not to finalize our proposal, stating that 47562 and 47563 describe more complex surgical procedures and both have a 090-day global period while 47560 has a 000-day global period.

Response: We acknowledge that the codes have different global periods, but believe that questions remain about how these codes should be valued. Therefore, we are finalizing our proposal to review these codes as potentially misvalued codes.

CPT codes 55845 (Prostatectomy, retropubic radical, with or without nerve sparing; with bilateral pelvic lymphadenectomy, including external iliac, hypogastric, and obturator nodes) and 55866 (Laparoscopy, surgical prostatectomy, retropubic radial, including nerve sparing, includes robotic assistance, when performed) were proposed as potentially misvalued because the RVUs for the laparoscopic procedure (CPT 55866) are higher than those for the open procedure (CPT 55845) and we believe that, in general, a laparoscopic procedure would not require greater resources than the open procedure.

<u>Comment</u>: A few comments suggested that these codes were not potentially misvalued because the laparoscopic code (CPT 55866) does require a higher level of work than the open procedure (CPT 55845) so the codes are in the appropriate rank order. One commenter stated that they had submitted an action plan for the review of these codes at the October 2013 AMA RUC meeting, and suggested that we defer any action on these codes until the AMA RUC review process is complete. Another commenter agreed that they were potentially misvalued saying that we should pay the same rate for both codes.

Response: Although most of the commenters indicated that it was appropriate that RVUs be higher for CPT code 55866 (laparoscopic procedure) than for CPT code 55845 (open procedure), we believe that there is enough question about how these codes should be valued that we are finalizing the proposal to review these codes as potentially misvalued codes. We note that we consider AMA RUC recommendations through our usual review of potentially misvalued codes.

We proposed CPT 64566 (Posterior tibial neurostimulation, percutaneous needle electrode, single treatment, includes programming) as a potentially misvalued code because the current valuation is based

on the procedure being furnished by a physician, but we think that the procedure typically is furnished by auxiliary personnel with physician supervision (rather than by a physician).

<u>Comment</u>: We received a few comments stating that this code is not misvalued and urged us not to finalize our proposal. One commenter disagrees that CPT code 64566 is potentially misvalued and stated that the current work RVU of 0.60 is appropriate and should be maintained.

Response: We believe that further review is needed to determine if this procedure is typically performed by the physician, or the auxiliary personnel with physician supervision. Therefore, we are finalizing our proposal to review the codes described above as potentially misvalued codes.

We proposed CPT code 76942 (Ultrasonic guidance for needle placement (for example, biopsy, aspiration, injection, localization device), imaging supervision and interpretation) as a potentially misvalued code because of the high frequency with which it is billed with CPT code 20610 (Arthrocentesis, aspiration and/or injection; major joint or bursa (for example, shoulder, hip, knee joint, subacromial bursa). As we noted in the proposed rule, we are concerned about potential overutilization of these codes and it was suggested that the payment for CPT code 76942 and CPT code 20610 should be bundled to reduce the incentive for providers to always provide and bill separately for ultrasound guidance.

We also noted in the proposed rule that we were proposing to revise the direct PE inputs for CPT code 76942 because claims data shows that the procedure time assumption for CPT code 76942 is longer than that for the typical procedure with which the code is billed (CPT code 20610). The direct PE inputs and procedure time for CPT code 76942 are addressed in detail in section II.B.4.f. of this final rule with comment period. We further explained in the proposed rule that the discrepancy in procedure times and the resulting potentially inaccurate payment raises a fundamental concern regarding the incentive to furnish ultrasound guidance.

<u>Comment</u>: We received a comment saying that this code is undervalued, several comments indicating that the reduction of time and other inputs would be inappropriate and some comments suggesting that we should delay action until the AMA RUC can review and provide its recommendation.

Response: Based on the diversity of the comments received about the valuation of this code, we are finalizing our proposal to review it as a potentially misvalued code. This action is consistent with the comment recommending that we delay action until the AMA RUC acts because we routinely consider AMA RUC recommendations through our usual review of potentially misvalued codes. Thus, we would seek the AMA RUC recommendation before re-valuing.

As we noted in the proposed rule that given our concerns with CPT code 76942, we have similar concerns with other codes for ultrasound guidance. Accordingly, we proposed the following additional ultrasound guidance codes as potentially misvalued.

CPT Code	Short Descriptor
76930	Echo guide cardiocentesis
76932	Echo guide for heart biopsy
76936	Echo guide for artery repair
76940	US guide tissue ablation
76948	Echo guide ova aspiration
76950	Echo guidance radiotherapy
76965	Echo guidance radiotherapy

<u>Comment</u>: We received some comments asking us not to treat 76930, 76932, and 76936 as potentially misvalued codes stating that these codes are not misvalued but without providing information to support the contention. One commenter stated that 76936 should be removed from the list because it is not an image guidance technique used to supplement a surgical procedure.

Response: We agree that code 76936 is not a code used to supplement a surgical procedure and therefore does not raise the concerns we discussed in the proposed rule. Accordingly, it will not be included on the list of potentially misvalued codes. The comments on codes 76930 and 76932 provided insufficient information to persuade us that these codes should not be considered potentially misvalued. Given that the identification of a code as potentially misvalued merely assures that the current values are evaluated to determine whether changes are warranted, we are finalizing our proposal to consider codes 76930 and 76932 as potentially misvalued.

In summary, the following codes are finalized as potentially misvalued codes.

TABLE 13: Potentially Misvalued CPT Codes

CPT Code	Short Descriptor
21800	Treatment of rib fracture
22305	Closed tx spine process fx
27193	Treat pelvic ring fracture
33960	External circulation assist
33961	External circulation assist, each subsequent day
47560	Laparoscopy w/cholangio
47562	Laparoscopic cholecystectomy
47563	Laparo cholecystectomy/graph
55845	Extensive prostate surgery
55866	Laparo radical prostatectomy
64566	Neuroeltrd stim post tibial
76930	Echo guide cardiocentesis
76932	Echo guide for heart biopsy
76940	US guide tissue ablation
76942	Echo guide for biopsy
76948	Echo guide ova aspiration
76950	Echo guidance radiotherapy
76965	Echo guidance radiotherapy

We will accept public nominations of potentially misvalued codes with supporting documentation as described in section II.C.3.a. of this final rule with comment period in the CY 2015 proposed rule.

ii. Number of Visits and Physician Time in Selected Global Surgical Packages

In the CY 2013 proposed rule, we sought comments on methods of obtaining accurate and current data on E/M services furnished as part of a global surgical package. Commenters provided a variety of suggestions including setting the all surgical services to a 0-day global period, requiring all E/M services to be separately billed, validating the global surgical packages with the hospital Diagnosis-Related Group length of stay data, and setting auditable documentation standards for post-operative E/M services. In addition to the broader comments, the AMA RUC noted that many surgical procedures did not have the correct hospital and discharge day management services in the global period, resulting in incorrect times in the time file. The AMA RUC submitted post-operative visits and times for the services

that we had displayed with zero visits in the CMS time file with the CY 2013 proposed rule. The AMA RUC suggested that the errors may have resulted from the inadvertent removal of the visits from the time file in 2007. We responded to this comment in the CY 2013 final rule with comment period by saying that we would review this file and, if appropriate, propose modifications. We noted in the CY 2013 final rule with comment period that if time had been removed from the physician time file inadvertently, it would have resulted in a small impact on the indirect allocation of PE at the specialty level, but it would not have affected the physician work RVUs or direct PE inputs for these services. It would have a small impact on the indirect allocation of PE at the specialty level, which we would review when we explore this potential time file change.

After extensive review, we believe that the data were deleted from the time file due to an inadvertent error as noted by the AMA RUC. To correct this inadvertent error, in the CY2014 proposed rule, we proposed to replace the missing post-operative hospital E/M visit information and time for the 117 codes that were identified by the AMA RUC and displayed in Table 14. Thus, we believe this correction will populate the physician time file with data that, absent the inadvertent error, would have been present in the time file.

TABLE 14: Global Surgical Package Visits and Physician Time Changes

СРТ	GI - D - i -	Visits Ir	ncluded in	Global P	CY 2013	CY 2014	
Code	Code Short Descriptor		99232	99238	99291	Physician Time	Physician Time
19368	Breast reconstruction	4.00		1.00		712.00	770.00
19369	Breast reconstruction	3.00		1.00		657.00	690.00
20100	Explore wound neck	2.00		1.00		218.00	266.00
20816	Replantation digit complete	5.00		1.00		671.00	697.00
20822	Replantation digit complete	3.00		1.00		587.00	590.00
20824	Replantation thumb complete	5.00		1.00		646.00	690.00
20827	Replantation thumb complete	4.00		1.00		610.00	625.00
20838	Replantation foot complete	8.00		1.00		887.00	986.00

¹ We note that in the CY 2014 proposed rule, this table displayed only whole numbers of visits, although the actual time file and our ratesetting calculations use data to two places beyond the decimal point.

СРТ		Visits Ir	ncluded in	Global Pa	ackage ¹	CY 2013	CY 2014
Code	Short Descriptor	99231	99232	99238	99291	Physician Time	Physician Time
20955	Fibula bone graft microvasc	6.00		1.00	1.00	867.00	957.00
20969	Bone/skin graft microvasc	8.00		1.00		1018.00	1048.00
20970	Bone/skin graft iliac crest	8.00		1.00		958.00	988.00
20973	Bone/skin graft great toe	5.00		1.00		1018.00	988.00
21139	Reduction of forehead	1.00		1.00		400.00	466.00
21151	Reconstruct midface lefort	2.00		1.00	1.00	567.00	686.00
21154	Reconstruct midface lefort	2.50		1.00	1.50	664.00	853.00
21155	Reconstruct midface lefort	2.00		1.00	2.00	754.00	939.00
21175	Reconstruct orbit/forehead		1.00	1.00	2.00	549.00	767.00
21182	Reconstruct cranial bone		1.00	1.00	2.00	619.00	856.00
21188	Reconstruction of midface	1.00		1.00		512.00	572.00
22100	Remove part of neck vertebra	2.00		1.00		397.00	372.00
22101	Remove part thorax vertebra	3.00		1.00		392.00	387.00
22110	Remove part of neck vertebra	6.00		1.00		437.00	479.00
22112	Remove part thorax vertebra	6.50		1.00		507.00	530.00
22114	Remove part lumbar vertebra	6.50		1.00		517.00	530.00
22210	Revision of neck spine	7.00		1.00		585.00	609.00
22212	Revision of thorax spine	7.00		1.00		610.00	640.00
22214	Revision of lumbar spine	7.00		1.00		585.00	624.00
22220	Revision of neck spine	6.50		1.00		565.00	585.00
22222	Revision of thorax spine	7.50		1.00		630.00	651.00
22224	Revision of lumbar spine	7.50		1.00		620.00	666.00
22315	Treat spine fracture	1.00		1.00		257.00	252.00
22325	Treat spine fracture	5.50		1.00		504.00	528.00
22326	Treat neck spine fracture	5.50		1.00		452.00	480.00
22327	Treat thorax spine fracture	9.00		1.00		505.00	604.00
22548	Neck spine fusion	8.00		1.00	1.00	532.00	673.00
22556	Thorax spine fusion	3.00		1.00	1.00	525.00	557.00
22558	Lumbar spine fusion	2.00		1.00	1.00	502.00	525.00
22590	Spine & skull spinal fusion	3.00		1.00		532.00	501.00
22595	Neck spinal fusion	6.00		1.00		492.00	521.00
22600	Neck spine fusion	6.00		1.00		437.00	490.00
22610	Thorax spine fusion	7.50		1.00		468.00	549.00
22630	Lumbar spine fusion	3.00		1.00		501.00	487.00
22800	Fusion of spine	7.00		1.00		517.00	571.00
22802	Fusion of spine	4.00		1.00		552.00	538.00
22804	Fusion of spine	5.00		1.00		630.00	595.00
22808	Fusion of spine	5.00		1.00		553.00	530.00

СРТ	PT Short Descriptor		ncluded in	Global Pa	ackage ¹	CY 2013	CY 2014
Code	Short Descriptor	99231	99232	99238	99291	Physician Time	Physician Time
22810	Fusion of spine	5.00		1.00		613.00	595.00
22812	Fusion of spine	7.50		1.00		666.00	700.00
31582	Revision of larynx	8.00		1.00		489.00	654.00
32650	Thoracoscopy w/pleurodesis	2.00		1.00		322.00	290.00
32656	Thoracoscopy w/pleurectomy	3.00		1.00		419.00	377.00
32658	Thoracoscopy w/sac fb remove	1.00		1.00		362.00	330.00
32659	Thoracoscopy w/sac drainage	2.00		1.00		414.00	357.00
32661	Thoracoscopy w/pericard exc	1.00		1.00		342.00	300.00
32664	Thoracoscopy w/ th nrv exc	1.00		1.00		362.00	330.00
32820	Reconstruct injured chest	3.50		1.00	4.50	631.00	854.00
33236	Remove electrode/thoracotomy	4.00		1.00		258.00	346.00
33237	Remove electrode/thoracotomy	5.00		1.00		378.00	456.00
33238	Remove electrode/thoracotomy	5.00		1.00		379.00	472.00
33243	Remove eltrd/thoracotomy	5.00		1.00		504.00	537.00
33321	Repair major vessel	8.00		1.00		751.00	754.00
33332	Insert major vessel graft	8.00		1.00		601.00	604.00
33401	Valvuloplasty open	8.00		1.00		830.00	661.00
33403	Valvuloplasty w/cp bypass	8.00		1.00		890.00	638.00
33417	Repair of aortic valve	2.50		1.00	2.50	740.00	750.00
33472	Revision of pulmonary valve	0.50		1.00	4.50	665.00	780.00
33502	Coronary artery correction	2.50		1.00	2.50	710.00	688.00
33503	Coronary artery graft	5.50		1.00	2.50	890.00	838.00
33504	Coronary artery graft	4.50		1.00	2.50	740.00	789.00
33600	Closure of valve	6.00		1.00		800.00	628.00
33602	Closure of valve	6.00		1.00		770.00	628.00
33606	Anastomosis/artery-aorta	8.00		1.00		860.00	728.00
33608	Repair anomaly w/conduit	5.00		1.00		800.00	668.00
33690	Reinforce pulmonary artery	2.50		1.00	2.50	620.00	636.00
33702	Repair of heart defects	0.50		1.00	3.50	663.00	751.00
33722	Repair of heart defect	5.00		1.00		770.00	608.00
33732	Repair heart-vein defect	5.00		1.00		710.00	578.00
33735	Revision of heart chamber	2.50		1.00	3.50	740.00	770.00
33736	Revision of heart chamber	5.00		1.00		710.00	548.00
33750	Major vessel shunt	2.00		1.00	3.00	680.00	722.00
33764	Major vessel shunt & graft	1.50		1.00	3.50	710.00	750.00

СРТ	gl p ; .	Visits Ir	ncluded in	Global Pa	ackage ¹	CY 2013	CY 2014
Code	Short Descriptor	99231	99232	99238	99291	Physician Time	Physician Time
33767	Major vessel shunt	5.00		1.00		800.00	608.00
33774	Repair great vessels defect	0.50		1.00	6.50	845.00	998.00
33788	Revision of pulmonary artery	2.50		1.00	2.50	770.00	736.00
33802	Repair vessel defect	2.50		1.00	1.50	558.00	556.00
33803	Repair vessel defect	2.50		1.00	1.50	618.00	586.00
33820	Revise major vessel	1.00		1.00	1.00	430.00	414.00
33824	Revise major vessel	0.50		1.00	2.50	588.00	615.00
33840	Remove aorta constriction	1.50		1.00	2.50	588.00	639.00
33845	Remove aorta constriction	1.00		1.00	3.00	710.00	726.00
33851	Remove aorta constriction	2.00		1.00	3.00	603.00	700.00
33852	Repair septal defect	2.00		1.00	3.00	663.00	719.00
33853	Repair septal defect	8.00		1.00		800.00	668.00
33917	Repair pulmonary artery	5.00		1.00		740.00	608.00
33920	Repair pulmonary atresia	6.00		1.00		800.00	658.00
33922	Transect pulmonary artery	5.00		1.00		618.00	546.00
33974	Remove intra-aortic balloon	1.00		1.00		406.00	314.00
34502	Reconstruct vena cava	6.00		1.00		793.00	741.00
35091	Repair defect of artery	11.00		1.00	2.00	597.00	790.00
35694	Arterial transposition	2.00		1.00		468.00	456.00
35901	Excision graft neck	4.00		1.00		484.00	482.00
35903	Excision graft extremity	3.00		1.00		408.00	416.00
47135	Transplantation of liver	23.00		1.00		1501.00	1345.00
47136	Transplantation of liver	28.00		1.00		1301.00	1329.00
49422	Remove tunneled ip cath	1.00		1.00		154.00	182.00
49429	Removal of shunt	6.00		1.00		249.00	317.00
50320	Remove kidney living donor	4.00		1.00		480.00	524.00
50845	Appendico-vesicostomy	5.00		1.00		685.00	613.00
56632	Extensive vulva surgery	7.00		1.00		835.00	683.00
60520	Removal of thymus gland	2.00		1.00	2.00	406.00	474.00
60521	Removal of thymus gland	5.00		1.00		457.00	445.00
60522	Removal of thymus gland	7.00		1.00		525.00	533.00
61557	Incise skull/sutures	3.00		1.00		529.00	510.00
63700	Repair of spinal herniation	3.00		1.00		399.00	401.00
63702	Repair of spinal herniation	3.00		1.00		469.00	463.00
63704	Repair of spinal herniation	8.00		1.00		534.00	609.00
63706	Repair of spinal herniation	8.00		1.00		602.00	679.00

iii. Codes with Higher Total Medicare Payments in Office than in Hospital or ASC

In the CY 2014 proposed rule with comment period, we proposed to address nearly 200 codes that we believe to have misvalued resource inputs. These are codes for which the total PFS payment when furnished in an office or other nonfacility setting would exceed the total Medicare payment (the combined payment to the facility and the professional) when the service is furnished in a facility, either a hospital outpatient department or an ASC.

For services furnished in a facility setting we would generally expect the combined payment to the facility and the practitioner to exceed the PFS payment made to the professional when the service is furnished in the nonfacility setting. This payment differential is expected because it reflects the greater costs we would expect to be incurred by facilities relative to physicians furnishing services in offices and other non-facility settings. These greater costs are due to higher overhead resulting from differences in regulatory requirements and for facilities, such as hospitals, maintaining the capacity to furnish services 24 hours per day and 7 days per week. However, when we analyzed such payments, we identified nearly 300 codes that would result in greater Medicare payment in the nonfacility setting than in the facility setting. We believe these anomalous site-of-service payment differentials are the result of inaccurate resource input data used to establish rates under the PFS.

We proposed to address these misvalued codes by refining the PE methodology to limit the nonfacility PE RVUs for individual codes so that the total nonfacility PFS payment amount would not exceed the total combined payment under the PFS and the OPPS (or the ASC payment system) when the service is furnished in the facility setting.

Section II.B.3 discusses the comment received on this misvalued code proposal and our response to these comments.

4. Multiple Procedure Payment Reduction Policy

Medicare has long employed multiple procedure payment reduction (MPPR) policies to adjust payment to more appropriately reflect reduced resources involved with furnishing services that are frequently furnished together. Under these policies, we reduce payment for the second and subsequent services within the same MPPR category furnished in the same session or same day. These payment

reductions reflect efficiencies that typically occur in either the PE or professional work or both when services are furnished together. With the exception of a few codes that are always reported with another code, the PFS values services independently to recognize relative resources involved when the service is the only one furnished in a session. Although some of our MPPR policies precede the Affordable Care Act, MPPRs can address the fourth category of potentially misvalued codes identified in section 1848(c)(2)(K) of the Act, as added by the Affordable Care Act, which is "multiple codes that are frequently billed in conjunction with furnishing a single service" (see 75 FR 73216). The following sections describe the history of MPPRs and the services currently covered by MPPRs.

a. Background

Medicare has a longstanding policy to reduce payment by 50 percent for the second and subsequent surgical procedures furnished to the same beneficiary by a single physician or physicians in the same group practice on the same day, largely based on the presence of efficiencies in the PE and preand post-surgical physician work. Effective January 1, 1995, the MPPR policy, with this same percentage reduction, was extended to nuclear medicine diagnostic procedures (CPT codes 78306, 78320, 78802, 78803, 78806, and 78807). In the CY 1995 PFS final rule with comment period (59 FR 63410), we indicated that we would consider applying the policy to other diagnostic tests in the future.

Consistent with recommendations of MedPAC in its March 2005 Report to the Congress on Medicare Payment Policy, for CY 2006 PFS, we extended the MPPR policy to the TC of certain diagnostic imaging procedures furnished on contiguous areas of the body in a single session (70 FR 70261). This MPPR policy recognizes that for the second and subsequent imaging procedures furnished in the same session, there are some efficiencies in clinical labor, supplies, and equipment time. In particular, certain clinical labor activities and supplies are not duplicated for subsequent imaging services in the same session and, because equipment time and indirect costs are allocated based on clinical labor time, adjustment to those figures is appropriate as well.

The imaging MPPR policy originally applied to computed tomography (CT) and computed tomographic angiography (CTA), magnetic resonance imaging (MRI) and magnetic resonance

angiography (MRA), and ultrasound services within 11 families of codes based on imaging modality and body region, and only applied to procedures furnished in a single session involving contiguous body areas within a family of codes. Additionally, this MPPR policy originally applied to TC-only services and to the TC of global services, but not to professional component (PC) services.

There have been several revisions to this policy since it was originally adopted. Under the current imaging MPPR policy, full payment is made for the TC of the highest paid procedure, and payment for the TC is reduced by 50 percent for each additional procedure subject to this MPPR policy. We originally planned to phase in the imaging MPPR policy over a 2-year period, with a 25 percent reduction in CY 2006 and a 50 percent reduction in CY 2007 (70 FR 70263). However, section 5102(b) of the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109–171, enacted on December 20, 2006) amended the statute to place a cap on the PFS payment amount for most imaging procedures at the amount paid under the hospital OPPS. In view of this new OPPS payment cap, we decided in the CY 2006 PFS final rule with comment period that it would be prudent to retain the imaging MPPR at 25 percent while we continued to examine the appropriate payment levels (71 FR 69659). The DRA also exempted reduced expenditures attributable to the imaging MPPR policy from the PFS budget neutrality provision.

Effective July 1, 2010, section 1848(b)(4)(C) of the Act increased the MPPR on the TC of imaging services under the policy established in the CY 2006 PFS final rule with comment period from 25 to 50 percent. Section 1848(c)(2)(B)(v)(IV) of the Act exempted the reduced expenditures attributable to this further change from the PFS budget neutrality provision.

In the July 2009 U.S. Government Accountability Office (GAO) report entitled, Medicare

Physician Payments: Fees Could Better Reflect Efficiencies Achieved when Services are Provided

Together, the GAO recommended that we take further steps to ensure that fees for services paid under the PFS reflect efficiencies that occur when services are furnished by the same physician to the same beneficiary on the same day. The GAO report recommended the following: (1) expanding the existing imaging MPPR policy for certain services to the PC to reflect efficiencies in physician work for certain imaging services; and (2) expanding the MPPR to reflect PE efficiencies that occur when certain

nonsurgical, nonimaging services are furnished together. The GAO report also encouraged us to focus on service pairs that have the most impact on Medicare spending.

In its March 2010 report, MedPAC noted its concerns about mispricing of services under the PFS. MedPAC indicated that it would explore whether expanding the unit of payment through packaging or bundling would improve payment accuracy and encourage more efficient use of services. In the CY 2009 and CY 2010 PFS proposed rules (73 FR 38586 and 74 FR 33554, respectively), we stated that we planned to analyze nonsurgical services commonly furnished together (for example, 60 to 75 percent of the time) to assess whether an expansion of the MPPR policy could be warranted. MedPAC encouraged us to consider duplicative physician work, as well as PE, in any expansion of the MPPR policy.

Section 1848(c)(2)(K) of the Act specifies that the Secretary shall identify potentially misvalued codes by examining multiple codes that are frequently billed in conjunction with furnishing a single service, and review and make appropriate adjustments to their relative values. As a first step in applying this provision, in the CY 2010 final rule with comment period, we implemented a limited expansion of the imaging MPPR policy to additional combinations of imaging services.

Effective January 1, 2011, the imaging MPPR applies regardless of code family; that is, the policy applies to multiple imaging services furnished within the same family of codes or across families. This policy is consistent with the standard PFS MPPR policy for surgical procedures that does not group procedures by body region. The current imaging MPPR policy applies to CT and CTA, MRI and MRA, and ultrasound procedures furnished to the same beneficiary in the same session, regardless of the imaging modality, and is not limited to contiguous body areas.

As we noted in the CY 2011 PFS final rule with comment period (75 FR 73228), although section 1848(c)(2)(B)(v)(VI) of the Act specifies that reduced expenditures attributable to the increase in the imaging MPPR from 25 to 50 percent (effective for fee schedules established beginning with 2010 and for services furnished on or after July 1, 2010) are excluded from the PFS budget neutrality adjustment, it does not apply to reduced expenditures attributable to our policy change regarding additional code combinations across code families (noncontiguous body areas) that are subject to budget neutrality under

the PFS. The complete list of codes subject to the CY 2011 MPPR policy for diagnostic imaging services is included in Addendum F.

As a further step in applying the provisions of section 1848(c)(2)(K) of the Act, on January 1, 2011, we implemented an MPPR for therapy services. The MPPR applies to separately payable "always therapy" services, that is, services that are only paid by Medicare when furnished under a therapy plan of care. As we explained in the CY 2011 PFS final rule with comment period (75 FR 73232), the therapy MPPR does not apply to contractor-priced codes, bundled codes, or add-on codes.

This MPPR for therapy services was first proposed in the CY 2011 proposed rule (75 FR 44075) as a 50 percent payment reduction to the PE component of the second and subsequent therapy services for multiple "always therapy" services furnished to a single beneficiary in a single day. It applies to services furnished by an individual or group practice or "incident to" a physician's service. However, in response to public comments, in the CY 2011 PFS final rule with comment period (75 FR 73232), we adopted a 25 percent payment reduction to the PE component of the second and subsequent therapy services for multiple "always therapy" services furnished to a single beneficiary in a single day.

Subsequent to publication of the CY 2011 PFS final rule with comment period, section 3 of the Physician Payment and Therapy Relief Act of 2010 (PPTRA) (Pub. L. 111-286) revised the payment reduction percentage from 25 percent to 20 percent for therapy services for which payment is made under a fee schedule under section 1848 of the Act (which are services furnished in office settings, or non-institutional services). The payment reduction percentage remained at 25 percent for therapy services furnished in institutional settings. Section 4 of the PPTRA exempted the reduced expenditures attributable to the therapy MPPR policy from the PFS budget neutrality provision. Section 633 of the ATRA revised the reduction to 50 percent of the PE component for all settings, effective April 1, 2013. Therefore, full payment is made for the service or unit with the highest PE and payment for the PE component for the second and subsequent procedures or additional units of the same service is reduced by 50 percent for both institutional and non-institutional services.

This MPPR policy applies to multiple units of the same therapy service, as well as to multiple different "always therapy" services, when furnished to the same beneficiary on the same day. The MPPR applies when multiple therapy services are billed on the same date of service for one beneficiary by the same practitioner or facility under the same National Provider Identifier (NPI), regardless of whether the services are furnished in one therapy discipline or multiple disciplines, including physical therapy, occupational therapy, or speech-language pathology.

The MPPR policy applies in all settings where outpatient therapy services are paid under Part B. This includes both services that are furnished in the office setting and paid under the PFS, as well as institutional services that are furnished by outpatient hospitals, home health agencies, comprehensive outpatient rehabilitation facilities (CORFs), and other entities that are paid for outpatient therapy services at rates based on the PFS.

In its June 2011 Report to Congress, MedPAC highlighted continued growth in ancillary services subject to the in-office ancillary services exception. The in-office ancillary exception to the physician self-referral prohibition in section 1877 of the Act, also known as the Stark law, allows physicians to refer Medicare beneficiaries to their own group practices for designated health services, including imaging, radiation therapy, home health care, clinical laboratory tests, and physical therapy, if certain conditions are met. MedPAC recommended that we curb overutilization by applying a MPPR to the PC of diagnostic imaging services furnished by the same practitioner in the same session. As noted above, the GAO already had made a similar recommendation in its July 2009 report.

In continuing to apply the provisions of section 1848(c)(2)(K) of the Act regarding potentially misvalued codes that result from "multiple codes that are frequently billed in conjunction with furnishing a single service," in the CY 2012 final rule (76 FR 73071), we expanded the MPPR to the PC of Advanced Imaging Services (CT, MRI, and Ultrasound), that is, the same list of codes to which the MPPR on the TC of advanced imaging already applied. Thus, this MPPR policy now applies to the PC and the TC of certain diagnostic imaging codes. Specifically, we expanded the payment reduction currently applied to the TC to apply also to the PC of the second and subsequent advanced imaging

services furnished by the same physician (or by two or more physicians in the same group practice) to the same beneficiary in the same session on the same day. However, in response to public comments, in the CY 2012 PFS final rule with comment period, we adopted a 25 percent payment reduction to the PC component of the second and subsequent imaging services.

Under this policy, full payment is made for the PC of the highest paid advanced imaging service, and payment is reduced by 25 percent for the PC for each additional advanced imaging service furnished to the same beneficiary in the same session. This policy was based on the expected efficiencies in furnishing multiple services in the same session due to duplication of physician work, primarily in the pre- and post-service periods, but with some efficiencies in the intraservice period.

This policy is consistent with the statutory requirement for the Secretary to identify, review, and adjust the relative values of potentially misvalued services under the PFS as specified by section 1848(c)(2)(K) of the Act. This policy is also consistent with our longstanding policies on surgical and nuclear medicine diagnostic procedures, under which we apply a 50 percent payment reduction to second and subsequent procedures. Furthermore, it was responsive to continued concerns about significant growth in imaging spending, and to MedPAC (March 2010 and June 2011) and GAO (July 2009) recommendations regarding the expansion of MPPR policies under the PFS to account for additional efficiencies.

In the CY 2013 final rule (77 FR 68933), we expanded the MPPR to the TC of certain cardiovascular and ophthalmology diagnostic tests. Although we proposed a 25 percent reduction for both diagnostic cardiovascular and ophthalmology services, we adopted a 20 percent reduction for ophthalmology services in the final rule with comment period (77 FR 68941) in response to public comments. For diagnostic cardiovascular services, full payment is made for the procedure with the highest TC payment, and payment is reduced by 25 percent for the TC for each additional procedure furnished to the same patient on the same day. For diagnostic ophthalmology services, full payment is made for the procedure with the highest TC payment, and payment is reduced by 20 percent for the TC for each additional procedure furnished to the same patient on the same day.

We did not propose and are not adopting any new MPPR policies for CY 2014. However, we continue to look at expanding the MPPR based on efficiencies when multiple procedures are furnished together.

The complete list of services subject to the MPPRs on diagnostic imaging services, therapy services, diagnostic cardiovascular services and diagnostic ophthalmology services is shown in Addenda F, H, I, and J. We note that Addenda H, which lists services subject to the MPPR on therapy services, contains four new CPT codes. Specifically, CPT code 92521 (Evaluation of speech fluency), 92522 (Evaluate speech sound production), 92523 (Speech sound language comprehension) and 92524 (Behavioral and qualitative analysis of voice and resonance) are being added to the list. These codes replace CPT code 92506 (Speech/hearing evaluation) for CY 2014. Accordingly, CPT 92506 has been deleted from Addenda H. Like CPT 92506, these new codes are "always therapy" services that are only paid by Medicare when furnished under a therapy plan of care. Thus, like CPT 92506, they are subject to the MPPR for therapy services. They have been added to the list of services subject to the MPPR on therapy services on an interim final basis, and are open to public comment on this final rule with comment period.

C. Malpractice RVUs

Section 1848(c) of the Act requires that each service paid under the PFS be composed of three components: work, PE, and malpractice. From 1992 to 1999, malpractice RVUs were charge-based, using weighted specialty-specific malpractice expense percentages and 1991 average allowed charges. Malpractice RVUs for new codes after 1991 were extrapolated from similar existing codes or as a percentage of the corresponding work RVU. Section 4505(f) of the BBA, which amended section 1848(c) of the Act, required us to implement resource-based malpractice RVUs for services furnished beginning in 2000. Therefore, initial implementation of resource-based malpractice RVUs occurred in 2000.

The statute also requires that we review and, if necessary, adjust RVUs no less often than every 5 years. The first review and corresponding update of resource-based malpractice RVUs was addressed in the CY 2005 PFS final rule with comment period (69 FR 66263). Minor modifications to the methodology were addressed in the CY 2006 PFS final rule with comment period (70 FR 70153). In the CY 2010 PFS final rule with comment period, we implemented the second review and corresponding update of malpractice RVUs. For a discussion of the second review and update of malpractice RVUs, see the CY 2010 PFS proposed rule (74 FR 33537) and final rule with comment period (74 FR 61758).

As explained in the CY 2011 PFS final rule with comment period (75 FR 73208), malpractice RVUs for new codes, revised codes and codes with revised work RVUs (new/revised codes) effective before the next five-year review of malpractice RVUs (for example, effective CY 2011 through CY 2014, assuming that the next review of malpractice RVUs occurs for CY 2015) are determined either by a direct crosswalk from a similar source code or by a modified crosswalk to account for differences in work RVUs between the new/revised code and the source code. For the modified crosswalk approach, we adjust (or "scale") the malpractice RVU for the new/revised code to reflect the difference in work RVU between the source code and the new/revised work value (or, if greater, the clinical labor portion of the PE RVU) for the new code. For example, if the proposed work RVU for a revised code is 10 percent higher than the work RVU for its source code, the malpractice RVU for the revised code would be

increased by 10 percent over the source code malpractice RVU. This approach presumes the same risk factor for the new/revised code and source code but uses the work RVU for the new/revised code to adjust for the difference in risk attributable to the variation in work between the two services.

For CY 2014, we use this approach for determining malpractice RVUs for new/revised codes. A list of new/revised codes and the malpractice crosswalks used to determine their malpractice RVUs are in Sections II.E.2.c and 3.c in this final rule with comment period. The CY 2014 malpractice RVUs for interim final codes are being implemented in the CY 2014 PFS final rule with comment period. These RVUs are subject to public comment. After considering public comments, they will then be finalized in the CY 2015 PFS final rule with comment period.

D. Medicare Economic Index (MEI)

1. Revising of the Medicare Economic Index (MEI)

a. Background

The Medicare Economic Index (MEI) is authorized under section 1842(b)(3) of the Act, which states that prevailing charge levels beginning after June 30, 1973 may not exceed the level from the previous year except to the extent that the Secretary finds, on the basis of appropriate economic index data, that such a higher level is justified by year-to-year economic changes. Beginning July 1, 1975, and continuing through today, the MEI has met this requirement by reflecting the weighted-average annual price change for various inputs involved in furnishing physicians' services. The MEI is a fixed-weight input price index, with an adjustment for the change in economy-wide, private nonfarm business multifactor productivity. This index is comprised of two broad categories: (1) physicians' own time; and (2) physicians' practice expense (PE).

The current general form of the MEI was described in the November 25, 1992 **Federal Register** (57 FR 55896) and was based in part on the recommendations of a Congressionallymandated meeting of experts held in March 1987. Since that time, the MEI has been updated or
revised on four instances. First, the MEI was rebased in 1998 (63 FR 58845), which moved the
cost structure of the index from 1992 data to 1996 data. Second, the methodology for the
productivity adjustment was revised in the CY 2003 PFS final rule with comment period (67 FR
80019) to reflect the percentage change in the 10-year moving average of economy-wide private
nonfarm business multifactor productivity. Third, the MEI was rebased in 2003 (68 FR 63239),
which moved the cost structure of the index from 1996 data to 2000 data. Fourth, the MEI was

rebased in 2011 (75 FR 73262), which moved the cost structure of the index from 2000 data to 2006 data.

The terms "rebasing" and "revising," while often used interchangeably, actually denote different activities. Rebasing refers to moving the base year for the structure of costs of a price index, while revising relates to other types of changes such as changing data sources, cost categories, or price proxies used in the price index. For CY 2014, we proposed to revise the MEI based on the recommendations of the MEI Technical Advisory Panel (TAP). We did not propose to rebase the MEI and will continue to use the data from 2006 to estimate the cost weights, since these are the most recently available, relevant, and complete data we have available to develop these weights.

b. MEI Technical Advisory Panel (TAP) Recommendations

The MEI-TAP was convened to conduct a technical review of the MEI, including the inputs, input weights, price-measurement proxies, and productivity adjustment. After considering these issues, the MEI-TAP was asked to assess the relevance and accuracy of inputs relative to current physician practices. The MEI-TAP's analysis and recommendations were to be considered in future rulemaking to ensure that the MEI accurately and appropriately meets its intended statutory purpose.

The MEI-TAP consisted of five members and held three meetings in 2012: May 21; June 25; and July 11. It produced eight findings and 13 recommendations for consideration by CMS. Background on the MEI-TAP members, meeting transcripts for all three meetings, and the MEI-TAP's final report, including all findings and recommendations, are available at http://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/MEITAP.html. We have determined, as noted in the proposed rule, that it is possible to implement some of the recommendations

immediately, while more in-depth research is required to address several of the other recommendations.

For CY 2014, we proposed to implement 10 of the 13 recommendations made by the MEI-TAP. The remaining recommendations require more in-depth research, and we will continue evaluating these three recommendations and will propose any further changes to the MEI in future rulemaking. The CY 2014 changes only involve revising the MEI categories, cost shares, and price proxies. Again, we did not propose to rebase the MEI for CY 2014 since the MEI-TAP concluded that there is not a newer, reliable, or ongoing source of data to maintain the MEI.

c. Overview of Revisions

The MEI was last rebased and revised in the CY 2011 PFS final rule with comment period (75 FR 73262 – 73275). The current base year for the MEI is 2006, which means that the cost weights in the index reflect physicians' expenses in 2006. The details of the methodology used to determine the 2006 cost shares were provided in the CY 2011 PFS proposed rule and finalized in the CY 2011 PFS final rule with comment period (75 FR 40087 and 75 FR 73262, respectively). For CY 2014 we proposed to make the following revisions to the 2006-based MEI:

- (1) Reclassify and revise certain cost categories:
- Reclassify expenses for non-physician clinical personnel that can bill independently from non-physician compensation to physician compensation.
- Revise the physician wage and benefit split so that the cost weights are more in line
 with the definitions of the price proxies used for each category.

 Add an additional subcategory under non-physician compensation for health-related workers.

- Create a new cost category called "All Other Professional Services" that includes expenses covered in the current MEI categories: "All Other Services" and "Other Professional Expenses." The "All Other Professional Services" category would be further disaggregated into appropriate occupational subcategories.
- Create an aggregate cost category called "Miscellaneous Office Expenses" that would include the expenses for "Rubber and Plastics," "Chemicals," "All Other Products," and "Paper."
 - (2) Revise price proxies:
- Revise the price proxy for physician wages and salaries from the Average Hourly
 Earnings (AHE) for the Total Private Nonfarm Economy for Production and Nonsupervisory
 Workers to the ECI for Wages and Salaries, Professional and Related Occupations, Private
 Industry.
- Revise the price proxy for physician benefits from the ECI for Benefits for the Total

 Private Industry to the ECI for Benefits, Professional and Related Occupations, Private Industry.
- Use the ECI for Wages and Salaries and the ECI for Benefits of Hospital, Civilian workers (private industry) as the price proxies for the new category of non-physician health-related workers.
- Use ECIs to proxy the Professional Services occupational subcategories that reflect the type of professional services purchased by physicians' offices.
- Revise the price proxy for the fixed capital category from the CPI for Owners'
 Equivalent Rent of Residences to the PPI for Lessors of Nonresidential Buildings (NAICS 53112).

d. Revising Expense Categories in the MEI

We did not propose any changes in the methodology for estimating the cost shares as finalized in the CY 2011 PFS final rule with comment period (75 FR 73263 - 73267). For CY 2014, we proposed to revise the classification of certain expenses within the 2006-based MEI. The details of the proposed revisions and the MEI-TAP recommendation that is the impetus for each of the revisions can be found in the CY 2014 PFS proposed rule (78 FR 43312 - 43316). The following sections summarize the proposed revisions to the cost weights for CY 2014. (1) Overall MEI Cost Weights.

Table 15 lists the set of mutually exclusive and exhaustive cost categories and weights that were proposed for CY 2014. A comparison of the proposed revised MEI cost categories and cost shares to the 2006-based MEI cost categories and cost shares as finalized in the CY 2011 PFS final rule can be found at 78 FR 43312-43313.

Based on the proposed revisions to the MEI for CY 2014, the proposed physician compensation cost weight under the revised MEI is 2.600 percentage points higher than the physician compensation weight in the current MEI. This change occurs because of the reclassification of expenses for non-physician clinical staff that can bill independently from non-physician compensation to physician compensation. This change lowers the PE cost weight by 2.600 percent as well, all of which comes from a lower weight for non-physician compensation. The remaining MEI cost weights are unchanged.

The proposed revised MEI includes four new detailed cost categories and two new sub-aggregate cost categories. The new detailed cost categories are:

- Health-related, non-physician wages and salaries.
- Professional, scientific, and technical services.

• Administrative support and waste management services.

• All other services.

The new sub-aggregate categories are:

- Non-health, non-physician wages.
- Miscellaneous office expenses.

The proposed revised MEI excludes two sub-aggregate categories that were included in the current 2006-based MEI. The sub-aggregate categories removed are:

- Office expenses.
- Drugs & supplies.

TABLE 15: Revised 2006 MEI Cost Categories and, Weights

Revised MEI (2006=100), CY2014	
Revised Cost Category	Revised Weights
Physician Compensation	50.866%
Wages and Salaries	43.641%
Benefits	7.225%
Practice Expense	49.134%
Non-physician compensation	16.553%
Non-physician wages	11.885%
Non-health, non-physician wages	7.249%
Professional and Related	0.800%
Management	1.529%
Clerical	4.720%
Services	0.200%
Health related, non-physician wages	4.636%
Non-physician benefits	4.668%
Other Practice Expense	32.581%
Utilities	1.266%
Miscellaneous Office Expenses	2.478%
Chemicals	0.723%
Paper	0.656%
Rubber & Plastics	0.598%
All other products	0.500%
Telephone	1.501%
Postage	0.898%
All Other professional services	8.095%
Professional, scientific, & technical services	2.592%
Administrative support & waste management	3.052%
All other services	2.451%
Capital	10.310%
Fixed Capital	8.957%
Moveable Capital	1.353%
Professional Liability Insurance	4.295%
Medical Equipment	1.978%
Medical supplies	1.760%
Total MEI	100.000%

^{*} The term (2006=100) refers to the base year of the MEI.

(2) Physician Compensation (Own time).

The component of the MEI that reflects the physician's own time is represented by the net income portion of business receipts. The 2006 cost weight associated with the physician's own time (otherwise referred to as the Physician's Compensation cost weight) is based on 2006 AMA PPIS data for mean physician net income (physician compensation) for self-employed physicians and for the selected self-employed specialties. Expenses for employed physician compensation are combined with expenses for self-employed physician compensation to obtain an aggregate Physician Compensation cost weight. Based on this methodology, the Physician Compensation cost weight in the current MEI is 48.266 percent. For CY 2014, we proposed to reclassify the expenses for non-physician practitioners that can bill independently from the non-physician cost category in the MEI to the physician compensation cost category for several reasons:

- These types of practitioners furnish services that are similar to those furnished by physicians.
- If billing independently, these practitioners would be paid at a percentage of the physicians' services or in certain cases at the same rate as physicians.
- The expenses related to the work components for the RVUs would include work from clinical staff that can bill independently. Therefore, it would improve consistency with the RVU payments to include these expenses as physician compensation in the MEI.

The effect of moving the expenses related to clinical staff that can bill independently is to increase the physician compensation cost share by 2.600 percentage points and to reduce the non-physician compensation cost share by the same amount. The physician compensation cost

share for the proposed revised MEI is 50.866 percent compared to the physician compensation cost share of 48.266 percent in the current MEI.

Within the physician compensation cost weight, the MEI includes a separate weight for wages and salaries and a separate weight for benefits. Under the current 2006-based MEI, the ratio for wages and salaries, and benefits was calculated using data from the PPIS. -

Based on MEI-TAP recommendation 3.1 we proposed to revise the wage and benefit split used for physician compensation. Specifically, we proposed to apply the distribution from the Statistics of Income (SOI) data to both self-employed and employed physician compensation. In reviewing the detailed AMA PPIS survey questions, it was clear that self-employed physician benefits were mainly comprised of insurance costs while other benefits such as physician retirement, paid leave, and payroll taxes were likely included in physician wages and salaries.

By definition, the price proxy used for physician benefits, which is an Employment Cost Index (ECI) concept, includes retirement savings. Thus, using the AMA PPIS data produced a definitional inconsistency between the cost weight and the price proxy. Therefore, we proposed to use the data on wages and salaries, and employee benefits from the SOI data for Offices of Physicians and Dentists for partnerships and corporations for both self-employed and employed physicians. From the SOI data, benefit expenses were estimated by summing the partnership data for retirement plans and employee benefit programs with corporation data for pension, profit-sharing plans and employee benefit programs. For 2006, the split between wages and salaries, and benefits was 85.8 percent and 14.2 percent, respectively. Retirement/pension plans account for about 60 percent of total benefits. The SOI data do not classify paid leave and supplemental pay as a benefit.

Combining the impact of classifying compensation for non-physicians that can bill independently as physician compensation with the use of the SOI data, the physician wages and salary cost share in the revised MEI is lower than the current MEI by 0.240 percentage points. These two methodological changes result in an increase in the physician benefit cost share in the revised MEI of 2.839 percentage points. As a result, the proposed physician wages and salary cost share for the revised MEI is 43.641 percent and the proposed physician benefit cost share for the revised MEI is 7.225 percent.

(3) Physician's Practice Expenses

To determine the PE cost weights, we use mean expense data from the 2006 PPIS survey. The derivation of the weights and categories for practice expenses is the same as finalized in the CY 2011 PFS final rule with comment period (75 FR 73264-73267), except where noted below.

(a) Non-physician Employee Compensation

For CY 2014 we proposed to exclude the expenses related to non-physician clinical staff that can bill independently from this cost category. Moving the expenses related to the clinical staff that can bill independently out of non-physician compensation costs decreases the share by 2.600 percentage points. The non-physician compensation cost share for the revised MEI is 16.553 percent compared to the current physician compensation cost share of 19.153 percent.

We are further proposed to use the same method as finalized in the CY 2011 PFS final rule to split the non-physician compensation between wages and benefits. For reference, we use 2006 BLS Employer Costs for Employee Compensation (ECEC) data for the Health Care and Social Assistance (private industry). Data for 2006 in the ECEC for Health Care and Social Assistance indicate that wages and benefits are 71.8 percent and 28.2 percent of compensation,

respectively. The non-physician wage and benefit cost shares for the revised MEI are 11.885 percent and 4.668 percent, respectively.

The current 2006-based MEI further disaggregated the non-physician wages into four occupational subcategories, the details of this method can be found in the CY 2011 PFS final rule with comment period (75 FR 73264-73265). Based on the MEI-TAP Recommendation 4.4, the Panel recommended the disaggregation of the non-physician compensation costs to include an additional category for health-related workers. The exact recommendation can be found at 78 FR 43314.

We proposed to implement this recommendation using expenses reported on the AMA PPIS for non-physician, non-health-related workers. The survey question asks for the expenses for: "non-clinical personnel involved primarily in administrative, secretarial or clerical activities (Including transcriptionists, medical records personnel, receptionists, schedulers and billing staff, coding staff, information technology staff, and custodial personnel)." Using this method, the proposed non-physician, non-health-related wage cost share for the revised MEI is 7.249 percent.

For wage costs of non-physician, health-related workers, the survey question asks for the expenses for: "other clinical staff, including RNs, LPNs, physicists, lab technicians, x-ray technicians, medical assistants, and other clinical personnel who **cannot** independently bill." Using this method, the proposed non-physician, health-related wage cost share for the revised MEI is 4.636 percent. Together the non-health and health-related, non-physician wage costs sum to be equal to the total non-physician wage share in the revised MEI of 11.885 percent.

We further proposed to disaggregate the non-physician, non-health-related wage cost weight of 7.249 percent into four occupational subcategories. The methodology is similar to that finalized in the CY 2011 PFS final rule with comment period (75 FR 73264), in that we are using

2006 Current Population Survey (CPS) data and 2006 BLS Occupational Employment Statistics (OES) data to develop cost weights for wages for non-physician, non-health-related occupational groups. We determined total annual earnings for offices of physicians using employment data from the CPS and mean annual earnings from the OES. To arrive at a distribution for these separate occupational categories (Professional & Related (P&R) workers, Managers, Clerical workers, and Service workers), we determined annual earnings for each using the Standard Occupational Classification (SOC) system. We then determined the overall share of the total for each. The proposed occupational distribution in the revised MEI is presented in Table 16. The comparison between the proposed revised distribution of non-physician payroll expense by occupational group to the prior comparison can be found in the CY 2014 PFS proposed rule at 78 FR43315.

TABLE 16: Percent Distribution of Non-physician Payroll Expense by Occupational Group: Revised 2006-Based MEI.

Revised MEI (2006=100),						
Revised						
Weight	Revised Cost Category					
16.553%	Non-physician compensation					
11.885%	Non-physician wages					
7.249%	Non-health, non-phys. wages					
0.800%	Professional and Related					
1.529%	Management					
4.720%	Clerical					
0.200%	Services					
4.636%	Health related, non-phys. wages					
4.668%	Non-physician benefits					

The health-related workers were previously included mainly in the Professional and Technical and Service Categories. The proposed reclassifications allow for health-related workers to be proxied by a health-specific ECI rather than an ECI for more general occupations.

(b) Other Practice Expense:

The remaining expenses in the MEI are categorized as Other Practice Expenses. In the current 2006-based MEI we had classified other PEs in one of the following subcategories:

Office Expenses; Drugs and Supplies; and All Other Professional Expenses. For CY 2014, we proposed to disaggregate these expenses in a way consistent with the MEI-TAP's recommendations, as detailed below.

We rely on the 2006 AMA PPIS data to determine the cost share for Other Practice Expenses. These expenses are the total of office expenses, medical supplies, medical equipment, Professional Liability Insurance (PLI), and all other professional expenses.

For the revised 2006-based MEI, we disaggregate Other Practice Expenses into 15 detailed subcategories as shown in Table 17.

TABLE 17: Revised Cost Categories for Other Practice Expense

Revised Cost Category	Revised Weight
Other Practice Expense	32.581%
Utilities	1.266%
Miscellaneous Office Expenses	2.478%
Chemicals	0.723%
Paper	0.656%
Rubber & Plastics	0.598%
All other products	0.500%
Telephone	1.501%
Postage	0.898%
All Other professional services	8.095%
Professional, Scientific, and Tech. Services	2.592%
Administrative support & waste mgmt	3.052%
All Other Services	2.451%
Capital	10.310%
Fixed	8.957%
Moveable	1.353%
Professional Liability Insurance	4.295%
Medical Equipment	1.978%
Medical supplies	1.760%

For most of these categories, we use the same method as finalized in the CY 2011 PFS final rule with comment period to estimate the cost shares. In particular, the cost shares for the following categories are derived directly from expense data reported on the 2006 AMA PPIS: PLI; Medical Equipment; and Medical Supplies. In each case, the cost shares remain the same as in the current MEI. Additionally, we continue to use the Bureau of Economic Analysis (BEA) 2002–Benchmark I/O data aged to 2006 to determine the cost weights for other expenses not collected directly from the AMA PPIS. The BEA 2002-Benchmark I/O data can be accessed at the following link: http://www.bea.gov/industry/io_benchmark.htm#2002data

The derivation of the cost weight for each of the detailed categories under Other Practice Expenses is provided in 78 FR 43315-43316. The following categories had no revisions proposed to the cost share weight and therefore reflect the same cost share weight as finalized in the CY 2011 final rule: Utilities, Telephone, Postage, Fixed Capital, Moveable Capital, PLI, Medical Equipment, and Medical Supplies. The following section provides a review of the categories for which we proposed revisions to the cost categories and cost share weights (Miscellaneous Office Expenses, and All Other Services).

• Miscellaneous Office Expenses: Based on MEI-TAP recommendation 3.4 we proposed to include an aggregate category of detailed office expenses that were stand-alone categories in the current 2006-based MEI. During the CY 2011 PFS proposed rule comment period, several commenters expressed confusion as to the relevance of these categories to their practice costs. The MEI-TAP discussed the degree of granularity needed in both the calculation and reporting of the MEI. The MEI-TAP concluded that it might be prudent to collapse some of the non-labor PE categories with other categories for presentation purposes.

All Other Professional Services: Based on MEI-TAP recommendation 3.3, we proposed to combine the All Other Services cost weight and All Other Professional Expenses into a single cost category. The proposed weight for the All Other Professional Services category is 8.095 percent, which is the sum of the current MEI weight for All Other Services (3.581 percent) and All Other Professional Expenses (4.513 percent), and is more in line with the GPCI Purchased Services index as finalized in the CY2012 PFS final rule with comment period (76 FR 73085).

We then proposed to further disaggregate the 8.095 percent of expenses into more detail based on the BEA I-O data, allowing for specific cost weights for services such as contract billing services, accounting, and legal services. We considered various levels of aggregation; however, in considering the level of aggregation, the available corresponding price proxies had to be considered. Given the price proxies that are available from the BLS Employment Cost Indexes (ECI), we proposed to disaggregate these expenses into three categories:

- NAICS 54 (Professional, Scientific, and Technical Services): The Professional, Scientific, and Technical Services sector comprises establishments that specialize in performing professional, scientific, and technical activities for others. These activities require a high degree of expertise and training. The establishments in this sector specialize according to expertise and provide these services to clients in a variety of industries, including but not limited to: legal advice and representation; accounting, and payroll services; computer services; management consulting services; and advertising services and have a 2.592 percent weight.
- NAICS 56 (Administrative and Support and Waste Management and Remediation

 Services): The Administrative and Support and Waste Management and Remediation Services
 sector comprises establishments performing routine support activities for the day-to-day

operations of other organizations. The establishments in this sector specialize in one or more of these support activities and provide these services to clients in a variety of industries including but not limited to: office administration; temporary help services; security services; cleaning and janitorial services; and trash collection services. These services have a 3.052 percent weight.

• All Other Services, a residual category of these expenses: The residual All Other Services cost category is mostly comprised of expenses associated with service occupations, including but not limited to: lab and blood specimen transport; catering and food services; collection company services; and dry cleaning services and have a 2.451 percent weight.

2. Selection of Price Proxies for Use in the MEI

After developing the cost category weights for the revised 2006-based MEI, we reviewed all the price proxies based on the recommendations from the MEI-TAP. As was the case in the development of the current 2006-based MEI, most of the proxy measures we considered are based on BLS data and are grouped into one of the following four categories:

- <u>Producer Price Indices (PPIs)</u>: PPIs measure price changes for goods sold in markets other than retail markets. These fixed-weight indexes are measures of price change at the intermediate or final stage of production. They are the preferred proxies for physician purchases as these prices appropriately reflect the product's first commercial transaction.
- Consumer Price Indices (CPIs): CPIs measure change in the prices of final goods and services bought by consumers. Like the PPIs, they are fixed weight indexes. Since they may not represent the price changes faced by producers, CPIs are used if there are no appropriate PPIs or if the particular expenditure category is likely to contain purchases made at the final point of sale.

• Employment Cost Indices (ECIs) for Wages & Salaries: These ECIs measure the rate of change in employee wage rates per hour worked. These fixed-weight indexes are not affected by employment shifts among industries or occupations and thus, measure only the pure rate of change in wages.

• Employment Cost Indices (ECIs) for Employee Benefits: These ECIs measure the rate of change in employer costs of employee benefits, such as the employer's share of Social Security taxes, pension and other retirement plans, insurance benefits (life, health, disability, and accident), and paid leave. Like ECIs for wages & salaries, the ECIs for employee benefits are not affected by employment shifts among industries or occupations.

When choosing wage and price proxies for each expense category, we evaluate the strengths and weaknesses of each proxy variable using the following four criteria.

- Relevance: The price proxy should appropriately represent price changes for specific goods or services within the expense category. Relevance may encompass judgments about relative efficiency of the market generating the price and wage increases.
- Reliability: If the potential proxy demonstrates a high sampling variability, or inexplicable erratic patterns over time, its viability as an appropriate price proxy is greatly diminished. Notably, low sampling variability can conflict with relevance—since the more specifically a price variable is defined (in terms of service, commodity, or geographic area), the higher the possibility of high sampling variability. A well-established time series is also preferred.
- <u>Timeliness of actual published data</u>: For greater granularity and the need to be as timely as possible, we prefer monthly and quarterly data to annual data.

• <u>Public availability</u>: For transparency, we prefer to use data sources that are publicly available.

The price proxy selection for every category in the proposed revised MEI is detailed in 78 FR 43316-43319. Below we discuss the price and wage proxies for each cost category in the proposed revised MEI.

- a. Physician Compensation (Physician's Own Time)
- (1) Physician Wages and Salaries

Based on recommendations from the MEI-TAP, we proposed to use the ECI for Wages and Salaries for Professional and Related Occupations (Private Industry) (BLS series code CIU2020000120000I) to measure price growth of this category in the revised 2006-based MEI. The current 2006-based MEI used Average Hourly Earnings (AHE) for Production and Non-Supervisory Employees for the Private Nonfarm Economy.

The MEI-TAP had two recommendations concerning the price proxy for physician Wages and Salaries. The first recommendation from the MEI-TAP was Recommendation 4.1, which stated that: "...OACT revise the price proxy associated with Physician Wages and Salaries from an Average Hourly Earnings concept to an Employment Cost Index concept." AHEs are calculated by dividing gross payrolls for wages and salaries by total hours. The AHE proxy was representative of actual changes in hourly earnings for the nonfarm business economy, including shifts in employment mix. The recommended alternative, the ECI concept, measures the rate of change in employee wage rates per hour worked. ECIs measure the pure rate of change in wages by industry and/or occupation and are not affected by shifts in employment mix across industries and occupations. The MEI-TAP believed that the ECI concept better reflected physician wage trends compared to the AHE concept.

The second recommendation related to the price proxy for physician wages and salaries was Recommendation 4.2, which stated that:

"CMS revise the price proxy associated with changes in Physician Wages and Salaries to use the Employment Cost Index for Wages and Salaries, Professional and Related, Private
Industry. The Panel believes this change would maintain consistency with the guidance provided in the 1972 Senate Finance Committee report titled 'Social Security Amendments of 1972,' which stated that the index should reflect changes in practice expenses and 'general earnings.'
In the event this change would be determined not to meet the legal requirement that the index reflect "general earnings," the Panel recommended replacing the current proxy with the Employment Cost Index for Wages and Salaries, All Workers, Private Industry." The Panel believed this change would maintain consistency with the guidance provided in the 1972 Senate Finance Committee report titled "Social Security Amendments of 1972," which stated that the index should reflect changes in practice expenses and "general earnings."

We agree that switching the proxy to the ECI for Wages and Salaries for Professional and Related Occupations would be consistent with the authority provided in the statute and reflect a wage trend more consistent with other professionals that receive advanced training.

Additionally, we believe the ECI is a more appropriate concept than the AHE because it can isolate wage trends without being impacted by the change in the mix of employment.

(2) Physician Benefits

The MEI-TAP states in Recommendation 4.3 that, "...any change in the price proxy for Physician Wages and Salaries be accompanied by the selection and incorporation of a Physician Benefits price proxy that is consistent with the Physician Wages and Salaries price proxy." We

² U.S. Senate, Committee on Finance, *Social Security Amendments of 1972*. "Report of the Committee on Finance United States Senate to Accompany H.R. 1," September 26, 1972, p. 191.

proposed to use the ECI for Benefits for Professional and Related Occupations (Private Industry) to measure price growth of this category in the revised 2006-based MEI. The ECI for Benefits for Professional and Related Occupations is derived using BLS's Total Compensation for Professional and Related Occupations (BLS series ID CIU2010000120000I) and the relative importance of wages and salaries within total compensation. We believe this series is technically appropriate because it better reflects the benefit trends for professionals requiring advanced training. The current 2006-based MEI market basket used the ECI for Total Benefits for the Total Private Industry.

- b. Practice Expense
- (1) Non-Physician Employee Compensation
- (a) Non-Physician Wages and Salaries
- (i) Non-Physician, Non-Health-Related Wages and Salaries
- <u>Professional and Related</u>: We proposed to continue using the ECI for Wages and Salaries for Professional and Related Occupation (Private Industry) (BLS series code CIU2020000120000I) to measure the price growth of this cost category.
- Management: We proposed to continue using the ECI for Wages and Salaries for Management, Business, and Financial (Private Industry) (BLS series code CIU2020000110000I) to measure the price growth of this cost category.
- <u>Clerical</u>: We proposed to continue using the ECI for Wages and Salaries for Office and Administrative Support (Private Industry) (BLS series code CIU2020000220000I) to measure the price growth of this cost category. This is the same proxy used in the current 2006-based MEI.

<u>Services</u>: We proposed to continue using the ECI for Wages and Salaries for Service
 Occupations (Private Industry) (BLS series code CIU2020000300000I) to measure the price growth of this cost category.

(ii) Non-physician, Health-Related Wages and Salaries

In Recommendation 4.4, the MEI-TAP "...recommend[ed] the disaggregation of the Non-Physician Compensation costs to include an additional category for health-related workers. This disaggregation would allow for health-related workers to be separated from non-healthrelated workers. CMS should rely directly on PPIS data to estimate the health-related nonphysician compensation cost weights. The non-health, non-physician wages should be further disaggregated based on the Current Population Survey and Occupational Employment Statistics data. The new health-related cost category should be proxied by the ECI, Wages and Salaries, Hospital (NAICS 622), which has an occupational mix that is reasonably close to that in physicians' offices. The Non-Physician Benefit category should be proxied by a composite benefit index reflecting the same relative occupation weights as the non-physician wages." We proposed to use the ECI for Wages and Salaries for Hospital Workers (Private Industry) (BLS series code CIU2026220000000I) to measure the price growth of this cost category in the final revised 2006-based MEI. The ECI for Hospital workers has an occupational mix that approximates that in physicians' offices. This cost category was not broken out separately in the current 2006-based MEI.

(b) Non-Physician Benefits

We proposed to continue using a composite ECI for non-physician employee benefits in the revised 2006-based MEI. However, we also proposed to expand the number of occupations from four to five by adding detail on Non-Physician Health-Related Benefits. The weights and

price proxies for the composite benefits index will be revised to reflect the addition of the new category. Table 18 lists the five ECI series and corresponding weights used to construct the revised composite benefit index for non-physician employees in the revised 2006-based MEI.

TABLE 18: CMS Composite Price Index for Non-physician Employee Benefits in the Revised 2006-Based MEI

ECI Series	2006 Weight
	(%)
Benefits for Professional and Related Occupation	7
(Private Industry)	
Benefits for Management, Business, and	12
Financial (Private Industry)	
Benefits for Office and Administrative Support	40
(Private Industry)	
Benefits for Service Occupations (Private	2
Industry)	
Benefits for Hospital Workers (Private Industry)	39

(3) Other Practice Expense

(a) All Other Professional Services

As discussed previously, MEI-TAP Recommendation 3.3 was that:

"...OACT create a new cost category entitled Professional Services that should consist of the All Other Services cost category (and its respective weight) and the Other Professional Expenses cost category (and its respective weight). The Panel further recommends that this category be disaggregated into appropriate occupational categories consistent with the relevant price proxies." We are proposed to implement this recommendation in the revised 2006-based MEI using a cost category titled "All Other Professional Services." Likewise, the MEI-TAP stated in Recommendation 4.7 that "...price changes associated with the Professional Services category be proxied by an appropriate blend of Employment Cost Indexes that reflect the types of professional services purchased by physician offices." We agree with this recommendation

and proposed to use the following price proxies for each of the new occupational categories:

• <u>Professional, Scientific, and Technical Services</u>: We proposed to use the ECI for Total Compensation for Professional, Scientific, and Technical Services (Private Industry) (BLS series code CIU2015400000000I) to measure the price growth of this cost category. This cost category was not broken out separately in the current 2006-based MEI.

- Administrative and Support Services: We proposed to use the ECI for Total
 Compensation for Administrative, Support, Waste Management, and Remediation Services
 (Private Industry) (BLS series code CIU2015600000000I) to measure the price growth of this
 cost category. This cost category was not broken out separately in the current 2006-based MEI.
- All Other Services: We proposed to use the ECI for Compensation for Service
 Occupations (Private Industry) (BLS series code CIU2010000300000I) to measure the price growth of this cost category.
- (b) Miscellaneous Office Expenses
- <u>Chemicals</u>: We proposed to continue using the PPI for Other Basic Organic Chemical Manufacturing (BLS series code #PCU32519–32519) to measure the price growth of this cost category.
- <u>Paper</u>: We proposed to continue using the PPI for Converted Paper and Paperboard
 (BLS series code #WPU0915) to measure the price growth of this cost category.
- Rubber & Plastics: We proposed to continue using the PPI for Rubber and Plastic Products (BLS series code #WPU07) to measure the price growth of this cost category.
- All Other Products: We proposed to continue using the CPI-U for All Products less
 Food and Energy (BLS series code CUUR0000SA0L1E) to measure the price growth of this cost category.

• <u>Utilities</u>: We proposed to continue using the CPI for Fuel and Utilities (BLS series code CUUR0000SAH2) to measure the price growth of this cost category.

- <u>Telephone</u>: We proposed to continue using the CPI for Telephone Services (BLS series code CUUR0000SEED) to measure the price growth of this cost category.
- <u>Postage</u>: We proposed to continue using the CPI for Postage (BLS series code
 CUUR0000SEEC01) to measure the price growth of this cost category.
- Fixed Capital: In Recommendation 4.5, "The Panel recommends using the Producer Price Index for Lessors of Nonresidential Buildings (NAICS 53112) for the MEI Fixed Capital cost category as it represents the types of fixed capital expenses most likely faced by physicians. The MEI-TAP noted the volatility in the index, which is greater than the Consumer Price Index for Owners' Equivalent Rent of Residences. This relative volatility merits ongoing monitoring and evaluation of alternatives." We are proposed to use the PPI for Lessors of Nonresidential Buildings (BLS series code PCU531120531120) to measure the price growth of this cost category in the revised 2006-based MEI. The current 2006-based MEI used the CPI for Owner's Equivalent Rent. We believe the PPI for Lessors of Nonresidential Buildings is more appropriate as fixed capital expenses in physician offices should be more congruent with trends in business office space costs than residential costs.
- Moveable Capital: In Recommendation 4.6, the MEI-TAP states that "...CMS conduct research into and identify a more appropriate price proxy for Moveable Capital expenses. In particular, the MEI-TAP believes it is important that a proxy reflect price changes in the types of non-medical equipment purchased in the production of physicians' services, as well as the price changes associated with Information and Communication Technology expenses (including both hardware and software)." We intend to continue to investigate possible data

sources that could be used to proxy the physician expenses related to moveable capital in more detail. However, we proposed to continue using the PPI for Machinery and Equipment (series code WPU11) to measure the price growth of this cost category in the revised 2006-based MEI.

• Professional Liability Insurance: Unlike the other price proxies based on data from BLS and other public sources, the proxy for PLI is based on data collected directly by CMS from a sample of commercial insurance carriers. The MEI-TAP discussed the methodology of the CMS PLI index, as well as considered alternative data sources for the PLI price proxy, including information available from BLS and through state insurance commissioners. MEI-TAP Finding 4.3 states:

"The Panel finds the CMS-constructed professional liability insurance price index used to proxy changes in professional liability insurance premiums in the MEI represents the best currently available method for its intended purpose. The Panel also believes the pricing patterns of commercial carriers, as measured by the CMS PLI index, are influenced by the same driving forces as those observable in policies underwritten by physician-owned insurance entities; thus, the Panel believes the current index appropriately reflects the price changes in premiums throughout the industry." Given this MEI-TAP finding, we proposed to continue using the CMS Physician PLI index to measure the price growth of this cost category in the revised 2006-based MEI.

- <u>Medical Equipment</u>: We proposed to continue using the PPI for Medical Instruments and Equipment (BLS series code WPU1562) as the price proxy for this category.
- Medical Materials and Supplies: We proposed to continue using a blended index comprised of a 50/50 blend of the PPI for Surgical Appliances (BLS series code WPU156301) and the CPI–U for Medical Equipment and Supplies (BLS series code CUUR0000SEMG).

TABLE 19: Revised 2006-Based MEI Cost Categories, Weights, and Price Proxies

Cost Category	2006 Weight	Price Proxy
Total MEI	100.000%	
Physician Compensation	50.866%	
Wages and Salaries	43.641%	ECI - Wages and salaries - Professional and
		Related (Private)
Benefits	7.225%	ECI - Benefits - Professional and Related
		(Private)
Practice Expense	49.134%	
Non-physician	16.553%	
Compensation		
Non-physician Wages	11.885%	
Non-health, non-	7.249%	
physician wages		
Professional and	0.800%	ECI - Wages And Salaries - Professional and
Related		Related (Private)
Management	1.529%	ECI - Wages And Salaries - Management,
		Business, and Financial (Private)
Clerical	4.720%	ECI - Wages And Salaries - Office and Admin.
		Support (Private)
Services	0.200%	ECI - Wages And Salaries - Service Occupations
		(Private)
Health related, non-phys.	4.636%	ECI - Wages and Salaries - Hospital (Private)
Wages		
Non-physician Benefits	4.668%	Composite Benefit Index
Other Practice Expense	32.581%	
Miscellaneous Office	2.478%	
Expenses		
Chemicals	0.723%	PPI - Other Basic Organic Chemical
		Manufacturing
Paper	0.656%	PPI - Converted Paper and Paperboard
Rubber and Plastics	0.598%	PPI - Rubber and Plastic Products
All other products	0.500%	CPI - All Items Less Food And Energy
Telephone	1.501%	CPI - Telephone
Postage	0.898%	CPI - Postage
All Other Professional	8.095%	
Services		
Prof., Scientific, and	2.592%	ECI - Compensation - Prof., Scientific, and

Cost Category	2006 Weight	Price Proxy
Tech. Svcs.		Technical (Private)
Admin. and Support	3.052%	ECI - Compensation - Admin., Support, Waste
Services		Management (Private)
All Other Services	2.451%	ECI - Compensation - Service Occupations
		(Private)
Capital		
Fixed Capital	8.957%	PPI - Lessors of Nonresidential Buildings
Moveable Capital	1.353%	PPI - Machinery and Equipment
Professional Liability	4.295%	CMS - Professional Liability Phys. Prem. Survey
Insurance		
Medical Equipment	1.978%	PPI - Medical Instruments and Equipment
Medical Supplies	1.760%	Composite - PPI Surgical Appliances & CPI-U
		Medical Supplies

3. Productivity Adjustment to the MEI

The MEI has been adjusted for changes in productivity since its inception. In the CY 2003 PFS final rule with comment period (67 FR 80019), we implemented a change in the way the MEI was adjusted to account for changes in productivity. The MEI used for the 2003 physician payment update incorporated changes in the 10-year moving average of private nonfarm business (economy-wide) multifactor productivity that were applied to the entire index. Previously, the index incorporated changes in productivity by adjusting the labor portions of the index by the 10-year moving average of economy-wide private nonfarm business labor productivity.

The MEI-TAP was asked to review this approach. In Finding 5.1, "[t]he Panel reviewed the basis for the current economy-wide multifactor productivity adjustment (Private Nonfarm Business Multifactor Productivity) in the MEI and finds such an adjustment continues to be appropriate. This adjustment prevents 'double counting' of the effects of productivity improvements, which would otherwise be reflected in both (i) the increase in compensation and other input price proxies underlying the MEI, and (ii) the growth in the number of physician

services performed per unit of input resources, which results from advances in productivity by individual physician practices."

Based on the MEI-TAP's finding, we proposed to continue to use the current method for adjusting the full MEI for multifactor productivity in the revised 2006-based MEI. As described in the CY 2003 PFS final rule with comment period, we believe this adjustment is appropriate because it explicitly reflects the productivity gains associated with all inputs (both labor and non-labor). We believe that using the 10-year moving average percent change in economy-wide multifactor productivity is appropriate for deriving a stable measure that helps alleviate the influence that the peak (or a trough) of a business cycle may have on the measure. The adjustment will be based on the latest available historical economy-wide nonfarm business multifactor productivity data as measured and published by BLS.

4. Results of Revisions on the MEI Update

Table 20 shows the average calendar year percent change from CY 2005 to CY 2013 for both the revised 2006-based MEI and the current 2006-based MEI, both excluding the productivity adjustment. The average annual percent change in the revised 2006-based MEI is 0.1 percent lower than the current 2006-based MEI over the 2005-2013 period. On an annual basis over this period, the differences vary by up to plus or minus 0.7 percentage point. In the two most recent years (CY 2012 and CY 2013), the annual percent change in the revised 2006-based MEI was within 0.1 percentage point of the percent change in the current 2006-based MEI. The majority of these differences over the historical period can be attributed to the revised price proxy for physician wages and salaries and benefits and the revised price proxy for fixed capital.

TABLE 20: Annual Percent Change in the Revised 2006-Based MEI, not including productivity adjustment and the

Current 2006-Based MEI, not including productivity adjustment*

Update Year	Revised 2006-based MEI excl. MFP	Current 2006- based MEI, excl. MFP
CY 2005	3.8	3.1
CY 2006	4.0	3.3
CY 2007	3.2	3.2
CY 2008	3.2	3.4
CY 2009	2.9	3.1
CY 2010	2.4	2.8
CY 2011	0.9	1.6
CY 2012	1.7	1.8
CY 2013	1.7	1.8
Avg. Change for CYs 2005-2013	2.6	2.7

^{*} Update year based on historical data through the second quarter of the prior calendar year. For example, the 2014 update is based on historical data through the second quarter 2013, prior to the MFP adjustment

5. Summary of Comments and the Associated Responses

<u>Comment</u>: Many commenters appreciate the efforts of CMS to implement the recommendations of the MEI-TAP. They agree with the MEI-TAP's analysis and recommendations and believe these changes successfully bring the "market basket" of MEI inputs up to date and improve the accuracy of the index going forward. Nearly all commenters supported the following proposals:

- The increase in the physician benefits cost weight in order to ensure consistency with the benefits price proxy.
- The use of professional workers' earnings as the price proxy for the physician compensation portion of the index. Specifically, the price proxies for physician wages would change from general economy-wide earnings to a wages index for "Professional and related occupations" and the price proxy for physician benefits would be changed from general economy-wide benefits to a benefit index for "Professional and related occupations."

• The use of commercial rent data for the fixed capital price proxy, replacing the CPI residential rent proxy.

- The creation of a health sector wage category within the index.
- The creation of an "all other professional services" category, encompassing purchased services such as contract billing, legal, and accounting services.

Response: We agree with the commenters that implementing the TAP recommendations identified above improve the accuracy of the index.

<u>Comment</u>: Several commenters concur with the proposal to reclassify expenses for non-physician clinical personnel that can bill independently from non-physician compensation to physician compensation. They agree with the proposal based on the reasons CMS outlines and because this policy is more consistent with how services by non-physician practitioners are treated in the resource-based relative value scale (RBRVS).

Response: We appreciate the commenters support for the decision to reclassify expenses related to non-physician clinical personnel that can bill independently from non-physician compensation to physician compensation. We also agree with the commenter that classifying the expenses with physician compensation is more consistent with how services by non-physician practitioners are treated in the RBRVS since services related to direct patient care from non-physician practitioners are reported with the work component in the RBRVS methodology. We also believe that non-physician practitioners will continue to perform services that are direct substitutes for services furnished by physicians, such as office visits.

<u>Comment</u>: Many commenters believe that it is not technically appropriate to reclassify all expenses for non-physician clinical personnel that can bill independently from non-physician compensation to physician compensation. They note that the MEI-TAP recommended that the

OACT consider "the extent to which those who can bill independently actually do so." They also note that non-physician clinical personnel often spend much of their time on activities other than providing services that are billed independently. They suggested that only the portion of the time the non-physician clinical personnel spend providing services that are billed independently should be reclassified to physician compensation. They believe that the increase in the physician compensation cost share by 2.600 percentage points, and the reduction in non-physician compensation by the same amount, is too high. The commenters encourage CMS to conduct real analysis of the time spent on activities that are billed independently prior to implementing this re-allocation of costs.

Response: We understand that non-physician clinical personnel may spend some of their time on activities other than providing services that are billed independently. We would note that physicians also spend some of their time on work that is not direct patient care. We proposed to only reclassify the expenses related to the non-physician clinical personnel that can bill independently; that is, we are not reclassifying the expenses for non-physician clinical personnel that cannot bill independently. We believe that the increase in physician compensation is technically correct.

The commenters suggested that the non-physician clinical staff that can bill independently spend much of their time on activities other than providing services that are billed separately; however, the commenters did not provide any evidence to support this claim. Based on part B claims data we have found that nurse practitioners and physician assistants bill Medicare for the same top HCPCS codes as other primary care specialties, including office/outpatient visits, subsequent hospital care, emergency department visits, and nursing facility care subsequent visits. Based on this, we do not believe further analysis is needed to

conclude that the non-physician practitioners that can bill independently are furnishing services that are substitutes for services furnished by physicians. As such, we continue to believe that it is appropriate to classify their costs in the physician compensation category.

<u>Comment:</u> A few commenters suggested that multiple states preclude non-physicians from practicing and billing independently and therefore the reclassification of expenses for these services would affect those states differently than the states where non-physician practitioners are allowed to practice and bill independently.

Response: We understand that state laws governing the practice rules for non-physician practitioners can vary by State; however, we do not believe that this is relevant to the decision to include in the physician compensation cost category the expenses for non-physician practitioners that can independently bill under Medicare. These expenses were collected on the AMA PPIS where we expect that physicians would have reported the expenses that coincided with the state laws for non-physician clinical staff for the state in which they practiced. For a state in which the laws do not permit non-physician practitioners to bill independently, the expenses would have been allocated to the category for clinical staff that cannot bill independently.

Comment: Several commenters questioned the implementation of the MEI-TAP recommendation concerning payroll for non-physician personnel. The commenters stated that the recommendation was more nuanced than we had conveyed and that it only directed CMS to evaluate making the change. The commenters suggested that the recommendation required CMS to consider several factors including but not limited to, the statutory definition of "physician" as it relates to the recommended change; how time for non-physician practitioners is currently treated in the PFS RVU methodology; whether there is evidence these non-physician

practitioners do not spend the majority of their time providing "physicians' services;" and the extent to which these practitioners actually do bill independently for the services they furnish.

Response: When evaluating the MEI-TAP recommendation 3.2 and formulating our proposal, we did consider the specific factors that the MEI-TAP included in the recommendation to reclassify the expenses related to non-physician clinical staff that can bill Medicare independently. However, we disagree with the commenters' interpretation that the recommendation intended CMS to only evaluate making the change. We believe that the intent of all of the recommendations of the MEI-TAP was for CMS to evaluate the recommendations and propose and implement those changes as soon as possible.

As we indicated in the proposed rule, there are several reasons for our proposal to reclassify these expenses which were: (1) these types of practitioners furnish services that are similar to those furnished by physicians; (2) if billing independently, these practitioners would be paid at a percentage of the physicians' services or in certain cases at the same rate as physicians; and (3) the expenses related to the work components for the RVUs would include work from clinical staff that can bill independently. Therefore, it would improve consistency with the RVU payments to include these expenses as physician compensation in the MEI.

In response to this comment, we explain further our consideration of each of the factors as follows:

First, we do not believe the definition of physician under current law limits CMS' ability to make the proposed change in the MEI. No provisions of the Social Security Act address the classification of costs in the MEI. The goal of the MEI is to appropriately estimate the change in the input prices of the goods and services used to furnish physician services over time.

Therefore, we believe that classifying costs for those non-physician practitioners that can bill

independently with physician compensation is the most technically appropriate classification, given their role in the healthcare delivery system today. We believe that since non-physician practitioners (NPPs) who bill independently furnish services that substitute for physician work and that the salary costs for these types of providers would grow at a similar rate to those of physicians, it is appropriate to classify these expenses within the physician compensation component of the MEI.

Second, the expenses for non-physician practitioners that can independently bill are reflected in the physician work component in the PFS RVU methodology since their services are substituting for physician work. Expenses for other clinical staff, including RNs, LPNs, physicists, lab technicians, x-ray technicians, medical assistants, and other clinical personnel who cannot independently bill are reported in the PE component in the RVU methodology.

Third, we have found no evidence that these types of providers do not spend the majority of their time performing "physicians' services," as defined under the PFS. We looked at 2012 claims data for the nurse practitioners (NPs) (specialty code 50) and physician assistants (PAs) (specialty code 97) and compared their top Part B HCPCS codes reported on claims to the top Part B HCPCS codes reported on claims of the following three physician specialties: General Practice (specialty code 01), Family Practice (specialty code 08), and Internal Medicine (specialty code 11). We found that 7 out of the 10 top HCPCS codes for PAs and NPs are the same as those reported for physicians in General Practice, Family Practice, and/or Internal Medicine. HCPCS code 99213 and 99214 (both codes for office/outpatient visits) were the top two HCPCS codes for all five specialties listed. Approximately 40 percent of claims for PAs and 50 percent of claims for NPs were for HCPCS codes that were also submitted by one of the three primary care specialties (general practice, family practice, and internal medicine). Based on this

Medicare claims analysis, we believe that these types of non-physician practitioners do spend the majority of their time performing "physicians' services."

Fourth, we believe that non-physician practitioners who are able to bill independently actually do so in the majority of circumstances where it is financially beneficial for the practice as a whole. We understand that different states may have different rules on how non-physician practitioners are permitted to furnish physician services; but, in general, if the non-physician practitioner can independently bill, particularly if the reimbursement for the service is similar to or the same as that provided to a physician, they usually do so. We reviewed data on mean annual wages published in the May 2012 Occupational Employment Survey (OES) (http://www.bls.gov/oes/current/oes_stru.htm), and found that wages for PAs and NPs are significantly higher than RNs and LPNs / LVNs. Specifically, the mean annual wages for OES Category 29-1071 "Physician Assistants" is \$92,460 and for OES Category 29-1171 "Nurse Practitioners" it is \$91,450 whereas for OES Category 29-1141 "Registered Nurses" it is \$67,930 and for OES Category 29-2061 "Licensed Practical and Licensed Vocational Nurses" it is \$42,400. In addition, wages for PAs and NPs are also significantly higher than technologist and technician wages. Select technologist and technician wages are OES Category 29-2051 "Dietetic Technicians" at \$28,680, OES Category 29-2052 "Pharmacy Technicians" at \$30,430, OES Category 29-2053 "Psychiatric Technicians" at \$33,140, OES Category 29-2054 "Respiratory Therapy Technicians" \$47,510, and OES Category 29-2055 "Surgical Technologists" at \$43,480. Given the significantly higher wages for PAs and NPs, we believe it makes economic sense for PAs and NPs to furnish and bill for "physicians' services" to the extent permitted by law rather than to serve as clinical staff members who only furnish services incident to a physician's services.

Comment: One commenter believes that the MEI is intended to be a reflection of physician compensation and physician expenses, and that it must conform to the definitions of "physician" and "physicians' services," which includes affirmation of the distinct definitions of physician and nurse practitioner. The commenter claims the reasons for our proposal fail to account for this foundational distinction between physicians and "physicians' services" as opposed to other types of practitioners and their services. The commenter believes that to lump the two definitions together, which is what we are doing, is not justifiable and in excess of authority.

Response: We disagree with the commenter that classifying the non-physician independent billers' expenses in the same category as the physician expenses "is not justifiable and in excess of authority." The definition of physician that exists under current law does not limit CMS' ability to make this change in the MEI. As mentioned previously, no provisions of the Social Security Act address the classification of costs in the MEI. We believe that since non-physician practitioners that bill independently serve as substitutes for physician work, and the growth in the salary costs for these types of providers would grow at a similar rate to physicians, then classifying the expenses related to non-physician practitioners that bill independently with physician compensation is the most technically appropriate classification, given their role in the healthcare delivery system today.

<u>Comment</u>: It is unclear to several commenters why the productivity assumptions for physicians are twice that used for the hospital outpatient department and ambulatory surgery centers. Although they understood that these are two different calculations, they found it hard to imagine that individual physicians would have twice the capability of increasing productivity than would facilities. They note that all of the productivity adjustments should be based on 10-

year averages of private non-farm business multifactor productivity growth, but the OPPS and ASC adjustments, are about half the MEI adjustment for CY 2014.

Response: The productivity adjustments included in the MEI and those that apply to ASCs and HOPDs are based on the 10-year moving average of economy-wide private nonfarm business multifactor productivity (MFP). The differences in the MFP adjustments between the ASC and HOPD payment systems and the PFS are the result of differences between the applicable statutes and the time period for which the adjustment is calculated.

MEI updates have been based on the latest historical data at the time of rulemaking since its inception. For the CY 2014 rule, the proposed MEI update of 0.7 percent includes an MFP adjustment of 0.9 percent, which is based on BLS data through 2011 that represents the latest historical data available at the time of rulemaking. The proposed MFP adjustment is based on the 10-year moving average of annual MFP growth from 2002-2011; and we would note that the annual MFP growth over the 2002-2004 time period was historically high.

The ASC and HOPD MFP adjustments, on the other hand, are required by law to be based on forecasts for the appropriate payment period, in this case through CY 2014. The forecasts of the MFP are completed by IHS Global Insight, Inc. (IGI). Accordingly, the MFP adjustment applicable to ASCs and HOPDs is based on the 10-year moving average of annual MFP growth from 2005-2014. A complete description of the methodology used to calculate the MFP for the MEI can be found in the CY 2012 PFS final rule with comment period (76 FR 73300).

<u>Comment</u>: One commenter disagrees with CMS' assessment that there is not a reliable, ongoing source of data from which to index cost data. CMS is currently basing the MEI on 2006 data yet it accepted and has now fully transitioned the results of the Physician Practice

Information Survey (PPIS) as of 2013. The data from PPIS was developed based on practice costs in 2008. They questioned why the data currently available would be any less reliable than was used the previous three times that CMS rebased the MEI. In fact, they claim that the PPIS data should be more reliable. The commenter acknowledges that data developed by the MGMA are derived primarily from large urban and suburban practices and do not adequately capture costs from small and solo practitioners who do not enjoy the same economies of scale and practice efficiencies afforded to larger groups. However, the commenter would support another updated survey of practice costs similar to PPIS that would also include any elements included within the MEI that were not previously captured. The commenter suggests that if the time and resources are going to go into such a study, the survey should include and be used to update all physician practice expenses.

Response: We believe the commenter misunderstood our statement. We do believe the AMA PPIS is a reliable data source; however, the PPIS is not an ongoing data source that is published regularly, such as the IPPS, SNF, and HHA cost reports. The 2006 AMA PPIS data were used to determine nine expenditure weights in the 2006-based MEI: physicians' earnings, physicians' benefits, employed physician payroll, non-physician compensation, office expenses, PLI, medical equipment, medical supplies, and other professional expenses. It continues to be the data source used in the CY 2014 proposed revisions to the MEI. At this time, the AMA is no longer conducting the PPIS survey.

We concur with the commenter's points regarding the issues pertaining to the MGMA data and also appreciate the commenter's support of conducting another practice cost survey similar to the PPIS. We will be looking into viable options for updating the MEI cost weights going forward.

Comment: Several commenters appreciated the efforts by CMS to convene the MEI-TAP, and urged the agency to continue work on the remaining issues the MEI-TAP identified including consideration of whether: (1) using self-employed physician data for the MEI cost weights continues to be the most appropriate approach; (2) additional data sources could allow more frequent updates to the MEI's cost categories and their respective weights; and (3) there is a more appropriate price proxy for Moveable Capital expenses. The commenter noted that CMS plans to continue to investigate these three issues and the commenter looks forward to working with CMS in that effort.

Response: We will continue to investigate possible options for the three remaining MEI-TAP recommendations as they require additional research regarding possible data sources. Any further changes to the MEI, in response to MEI-TAP recommendations, will be made through future notice and comment rulemaking.

Comment: One commenter noted that although the MEI-TAP recommended a number of data sources that could be considered to rebase the MEI, it was unable to identify a reliable, ongoing source of data to do so. The commenter recommended that CMS consider a sample cost reporting method rather than a survey similar to the American Medical Association's (AMA) Physician Practice Information Survey (PPIS) that took place between 2007 and 2008. The commenter noted that the PPIS was extraordinarily expensive for the AMA and was plagued by low response rates. In addition, the commenter noted that the disputed PPIS results led to significant payment reductions for cardiology. The commenter notes that CMS is already considering efforts to establish a cost report for provider-based clinics. The commenter suggests that this effort could be coupled with a sample of private practice clinics in order to better measure the MEI.

Response: We thank the commenter for the suggestion. We will be investigating possible data sources to use for the purpose of rebasing the MEI in the future. Our research will include the evaluation of multiple potential data sources including a sampling of clinics and/or physicians subject to agency resources. If reliable cost report data is collected for provider-based clinics in the future then we will analyze and consider its possible use at that time. We remind the commenter that any new study or survey we conduct would require approval through OMB's standard survey and auditing process (see "Standards and Guidelines for Statistical Surveys" http://www.whitehouse.gov/sites/default/files/omb/assets/omb/inforeg/pmc survey guidance 2006.pdf).

Comment: One commenter strongly supports the continued monitoring of physician productivity growth as it compares to economy-wide growth. The commenter notes that medical practices have been subjected to a number of regulatory requirements in recent years that likely impacted their productivity. To ensure compliance with these regulatory requirements, physicians often must take actions that reduce practice productivity, including hiring additional office staff, retaining attorneys for legal and regulatory compliance, and contracting with accountants and billing companies to ensure proper processing of claims. Monitoring of physician productivity growth is necessary to determine if the continued use of economy-wide productivity growth in the MEI is appropriate.

Response: At the June 25, 2012 MEI-TAP meeting, we presented estimates of physician-specific productivity from 1983 to 2010. These estimates used a resource-based methodology similar to that used by Charles Fisher to estimate physician office productivity from 1983-2004 as published in the Winter 2007 Health Care Financing Review. The MEI-TAP had the following finding regarding the physician-specific productivity estimates:

Finding 5.2: The Panel finds the measures of growth in physician-specific productivity are of interest for the purpose of comparing the structure of price increases for physician services versus other sectors of the economy. The Panel does not recommend using a physician-specific measure, but does believe that continued monitoring is appropriate. Use of physician-specific productivity growth to adjust economy-wide compensation growth in the MEI could introduce inconsistencies in the calculation of the MEI that could distort the results. The Panel concludes it is appropriate to continue to require that the accounting identity between input price growth, output price growth, and the productivity adjustment be maintained (as is approximated by the current version of the index).

Per the MEI-TAP's recommendation, we will continue to monitor trends in physician productivity on a periodic basis and how those trends move relative to economy-wide productivity.

Comment: A few commenters noted that it will remain difficult for practicing clinicians to reconcile changes in the MEI with their own practice cost increases. The projected increase in the proposed MEI for 2014 is just 0.7 percent, but this amount has been reduced by economywide productivity growth of 0.9 percent. Excluding the productivity adjustment, inflation for medical practices is projected to be 1.6 percent for 2014. In addition, as is the case with any price index, this amount does not take into account any change in the quantity of inputs (for example, changes in the number of staff that practices employ).

Response: We believe the MEI is the most technically appropriate index available to measure the price growth of inputs involved in furnishing physician services. We agree that the updates of the MEI do not take into account any change in the quantity of inputs, since it is not a cost index. The MEI-TAP was asked to consider whether the index should continue to be a

fixed-weight, Laspeyres-type index. The MEI-TAP concluded that there is not sufficient evidence that the proportions of costs represented by the index's inputs vary enough over short periods of time, nor was there a consistently updated data source available, to warrant or support a change from using the Laspeyres formulation.

Comment: One commenter believes that a driving flaw in the PE GPCI is the rent input and its weighting. The commenter indicates the proposed rule's CY 2014 cost share weight of 10.223 percent is not representative of the office rent cost share weights of other physicians. It is also not representative of what the MGMA's cost survey data seems to indicate is the national office rent cost weight.

Response: As stated in the proposed rule, the PE GPCI office rent portion (10.223 percent) includes the revised 2006-based MEI cost weights for fixed capital (reflecting the expenses for rent, depreciation on medical buildings and mortgage interest) and utilities. The methodology for determining the fixed capital cost weight (8.957 percent) and utilities cost weight (1.266) is described in the CY 2011 PFS final rule (75 FR 73265).

We believe the weights produced from the methodology are technically appropriate as it is based on the 2006 AMA PPIS data and other government data for NAICS 621A00 (Offices of physicians, dentists, and other health practitioners). We realize that although individual practice experience may vary, the MEI cost shares must reflect the cost structure of the average physician office.

<u>Comment</u>: One commenter supported the AMA's call for MEI recognition of the cost/staffing implications of ever-increasing private and governmental regulations upon medical practices.

Response: We believe the commenter is expressing that during the course of our future research into alternative data sources on physician expenses that we should try to find a data source that would measure the increased costs that regulations compliance imposes on physicians practice expenses (for example, additional staffing or costs associated with moving to more technically advanced record-keeping such as electronic health records (EHRs)). If we are able to identify an appropriate data source for physician expenses that is updated and published on a regular basis, then the associated costs will be reflected in the relative shares of the various cost categories. In order to determine cost shares for a year later than 2006 we would need an alternative data source that is reliable, representative, and collected on a more consistent, regular basis.

Comment: One commenter claimed that the BEA Input-Output (I-O) tables categorize cost components differently than do medical practices; that CMS' actuarial conclusions are difficult to follow; and the industry wide I-O tables do not appear to comport with MGMA cost survey findings for medical practices. The commenter also stated that BEA I-O tables seem more focused on and designed to address how the offices of healthcare professionals utilize products in various national industries for purposes of assessing the productivity of those industries rather than to measure cost components of a medical practice. In that regard, the commenter asserts that the use of the I-O tables in developing GPCI cost share weights seems not to be an apples-to-apples relationship.

Response: We disagree with the commenter's claim that the BEA I-O tables are only to be used for purposes of assessing productivity of those industries rather than to measure cost components. As stated on the BEA website

(http://www.bea.gov/scb/pdf/2007/10%20October/1007 benchmark io.pdf), the BEA I-O data are

based on the highest quality source data available. They provide an accurate and comprehensive picture of the inner workings of the economy, showing relationships among more than 400 industries and commodities. They facilitate the study of economic activity by providing a highly-detailed look at inter-industry activity. They also provide the detail that is essential in determining the quantity weights for price indexes such as the producer price index that is compiled by the Bureau of Labor Statistics (BLS). Therefore, our use of the BEA I-O data to derive the detailed cost weights for the MEI (and by extension the GPCI weights) is consistent with definition of and uses of the I-O data, as stated by BEA.

We would also note that CMS' examination of the MGMA cost data requested by the MEI-TAP found that the data: (1) reflected only group practice data (practices with greater than three physicians) rather than data for self-employed physician practices; (2) reflected more IDS and hospital-owned practices than physician-owned practices; (3) are not geographically representative; they are underrepresented in high-cost areas (NY, NJ, CA) and overrepresented in lower cost areas, such as the southern U.S.; and (4) are skewed toward primary care specialties relative to the universe of physician specialties. Additionally, the MGMA data are not publicly available. The BEA I-O data, on the other hand are based on detailed data from the quinquennial economic censuses that are conducted by the Bureau of the Census and show how industries interact at the detailed level; specifically, they show how approximately 500 industries provide input to, and use output from, each other to produce gross domestic product. The data we used in the construction of the MEI are representative of the entire broader industry as defined by NAICS 621A00, Offices of Physicians, Dentists and Other Health Professionals; and therefore we believe it is the most technically appropriate data source available to use to further disaggregate practice expenses within the MEI.

Comment: One commenter is concerned with CMS' proposal to use the Employment Cost Index (ECI) for Wages and Salaries for Hospital Workers (Private Industry) as a price proxy for Non-physician, Health-related staff compensation. The commenter does not agree with CMS' reasoning that the ECI for Hospital Workers has an occupational mix that is reasonably close to the occupational mix in physicians' offices. The commenter stated that they do not currently have an alternative price proxy suggestion.

Response: The purpose of the disaggregation of the Non-Physician Compensation costs to include an additional category for health-related workers was to be able to more accurately reflect the price inflation associated with these workers. There are limited health-related ECIs available. During the MEI-TAP discussions on July 11, 2012, this limitation was discussed (http://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/MEITAP.html).

We continue to believe that the ECI for Wages and Salaries for Hospital Workers (Private Industry) is the most technically appropriate proxy for the compensation price inflation faced by non-physician, health related staff in physician offices as this ECI reflects the highest proportion of health-related staff (as measured by the Occupational Employment Statistics data) compared to other ECIs. Should the commenter have alternative price proxy suggestions, we will consider them in future rulemaking.

<u>Comment</u>: Several commenters agree with the proposed change in the price proxy for Fixed Capital, since it represents the types of fixed capital expenses most likely faced by physicians.

Response: We agree with the commenters that the price proxy proposed for Fixed Capital is more representative of the types of fixed capital expenses faced by physicians.

6. Final CY 2014 Revisions to the MEI

In general, most commenters supported all of the proposed changes to the index. The one area where there was concern from commenters was with the proposal to reclassify expenses for non-physician practitioners that can independently bill from non-physician compensation to physician compensation. Based on the public comments, we did not find any reason to reconsider our proposal, nor did we find any compelling technical reason that we should not implement this revision to the MEI. Therefore, we are finalizing our proposal to reclassify these expenses from non-physician compensation to physician compensation in the MEI. The effect of moving the expenses related to clinical staff that can bill independently to physician compensation category is to increase the physician compensation cost share by 2.600 percentage points and reduce non-physician compensation costs by the same amount. The revisions we are finalizing include:

- Reclassifying expenses for non-physician clinical personnel that can bill independently from non-physician compensation to physician compensation.
- Revising the physician wage and benefit split so that the cost weights are more in line with the definitions of the price proxies used for each category.
- Adding an additional subcategory under non-physician compensation for healthrelated workers.
- Creating a new cost category called "All Other Professional Services" that includes expenses covered in the current MEI categories: "All Other Services" and "Other Professional Expenses." And further disaggregating the "All Other Professional Services" category into appropriate occupational subcategories.

 Creating an aggregate cost category called "Miscellaneous Office Expenses" that would include the expenses for "Rubber and Plastics," "Chemicals," "All Other Products," and "Paper."

- Revising the price proxy for physician wages and salaries from the Average Hourly
 Earnings (AHE) for the Total Private Nonfarm Economy for Production and Nonsupervisory
 Workers to the ECI for Wages and Salaries, Professional and Related Occupations, Private
 Industry.
- Revising the price proxy for physician benefits from the ECI for Benefits for the Total Private Industry to the ECI for Benefits, Professional and Related Occupations, Private Industry.
- Using the ECI for Wages and Salaries and the ECI for Benefits of Hospital, Civilian workers (private industry) as the price proxies for the new category of non-physician health-related workers.
- Using ECIs to proxy the Professional Services occupational subcategories that reflect the type of professional services purchased by physicians' offices.
- Revising the price proxy for the fixed capital category from the CPI for Owners'
 Equivalent Rent of Residences to the PPI for Lessors of Nonresidential Buildings (NAICS 53112).

Table 21 shows the final revised 2006-based MEI update for CY 2014 PFS, which is an increase of 0.8 percent. The CY 2014 MEI update would be the same if using the current 2006-based MEI. This update is based on historical data through the second quarter of 2013.

TABLE 21: Annual Percent Change in the CY 2014 Revised 2006-Based MEI and the Current 2006-Based MEI*

Update Year	Final Revised 2006- based MEI	Current 2006-based MEI
CY 2014	0.8	0.8

^{*}Based on historical data through the 2nd quarter 2013.

For the productivity adjustment, the 10-year moving average percent change adjustment for CY 2014 is 0.9 percent, which is based on the most historical data available from BLS at the time of the final rule, and reflects annual MFP estimates through 2012.

Table 22 shows the Cost Categories, Price Proxies, Cost Share Weights and the CY 2014 percent changes for each category in the revised 2006-based MEI. This table summarizes all of the final revisions to the MEI for CY2014.

TABLE 22: Annual Percent Change in the Revised MEI for CY 2014 (All Categories)¹

	(All Categories)	2006 Final	CY14
Revised Cost		Revised Cost	Update
Category	Revised Price Proxy	Weight ²	(percent) ⁵
MEI		100.000%	0.8
	10-yr moving average of Private		
	Nonfarm Business Multifactor		
MFP	Productivity	N/A	0.9
MEI without			
productivity			
adjustment		100.000%	1.7
Physician			
Compensation ³		50.866%	1.9
	ECI - Wages and salaries -		
Wages and Salaries	Professional and Related (private)	43.641%	1.9
	ECI - Benefits - Professional and		
Benefits	Related (private)	7.225%	2.2
Practice Expense		49.134%	1.4
Non-physician			
compensation		16.553%	1.7
Non-physician			
wages		11.885%	1.7
Non-health, non-			
physician wages		7.249%	1.8
Professional &	ECI - Wages And Salaries -		
Related	Professional and Related (Private)	0.800%	1.9
	ECI - Wages And Salaries -		
	Management, Business, and		
Management	Financial (Private)	1.529%	1.8
	ECI - Wages And Salaries - Office		
Clerical	and Administrative Support	4.720%	1.8

Revised Cost	D : 1D: D	2006 Final Revised Cost	CY14 Update
Category	Revised Price Proxy	Weight ²	(percent) ⁵
	(Private)		
~ .	ECI - Wages And Salaries - Service		
Services	Occupations (Private)	0.200%	1.5
Health related,	ECI - Wages and Salaries -Hospital		
non-physician wages	(civilian)	4.636%	1.4
Non-physician		4.66007	1.0
benefits	Composite Benefit Index	4.668%	1.9
Other Practice			
Expense		32.581%	1.2
Utilities	CPI Fuels and Utilities	1.266%	0.7
Miscellaneous			
Office Expenses		2.478%	0.3
	Other Basic Organic Chemical		
Chemicals	Manufacturing PPI325190	0.723%	-1.2
Paper	PPI for converted paper	0.656%	1.1
Rubber &			
Plastics	PPI for rubber and plastics	0.598%	0.5
All other	CPI - All Items Less Food And		
products	Energy	0.500%	1.9
Telephone	CPI for Telephone	1.501%	0.0
Postage	CPI for Postage	0.898%	4.9
All Other			
Professional Services		8.095%	1.8
Professional,			
Scientific, and Tech.	ECI - Compensation: Prof.		
Services	scientific, tech.	2.592%	1.7
Administrative			
and support & waste	ECI - Compensation Administrative	3.052%	1.9
All Other	ECI Compensation: Services		
Services	Occupations	2.451%	1.6
Capital	•	10.310%	0.7
	PPI for Lessors of nonresidential		
Fixed	buildings	8.957%	0.7
Moveable	PPI for Machinery and Equipment	1.353%	0.7
Professional	CMS - Prof. Liability. Phys. Prem.	1.50070	0.,
Liability Insurance ⁴	Survey	4.295%	1.5
Medical Equipment	2	1.978%	1.2
Tyrodical Equipment	Composite - PPI Surg. Appl. &	1.7/0/0	1.2
Medical supplies	CPIU Med. Supplies. (CY2006)	1.760%	1.0
	he latest available Bureau of Labor Statistics data on t		

¹ The estimates are based upon the latest available Bureau of Labor Statistics data on the 10-year moving average of BLS private nonfarm business multifactor productivity published on July 19, 2013 http://www.bls.gov/news.release/prod3.nr0.htm 2 The weights shown for the MEI components are the 2006 base-year weights, which may not sum to subtotals or totals because of rounding. The MEI is a fixed-weight, Laspeyres input price index whose category weights indicate the distribution of

expenditures among the inputs to physicians' services for CY 2006. To determine the MEI level for a given year, the price proxy level for each component is multiplied by its 2006 weight. The sum of these products (weights multiplied by the price index levels) yields the composite MEI level for a given year. The annual percent change in the MEI levels is an estimate of price change over time for a fixed market basket of inputs to physicians' services.

- 3 The measures of Productivity, Average Hourly Earnings, Employment Cost Indexes, as well as the various Producer and Consumer Price Indexes can be found on the Bureau of Labor Statistics (BLS) Web site at http://stats.bls.gov.
- 4 Derived from a CMS survey of several major commercial insurers.
- 5. Based on historical data through the 2nd quarter 2013.

N/A Productivity is factored into the MEI as a subtraction from the total index growth rate; therefore, no explicit weight exists for productivity in the MEI.

E. Establishing RVUs for CY 2014

Section 1848(c)(2)(B) of the Act requires that we review RVUs for physicians' services no less often than every 5 years. Under section 1848(c)(2)(K) of the Act (as added by section 3134 of the Affordable Care Act), we are required to identify and revise RVUs for services identified as potentially misvalued. To facilitate the review and appropriate adjustment of potentially misvalued services, section 1848(c)(2)(K)(iii) specifies that the Secretary may use existing processes to receive recommendations; conduct surveys, other data collection activities, studies, or other analyses as the Secretary determined to be appropriate; and use analytic contractors to identify and analyze potentially misvalued services, conduct surveys or collect data. In accordance with section 1848(c)(2)(K)(iii) of the Act, we identify potentially misvalued codes, and develop and propose appropriate adjustments to the RVUs, taking into account the recommendations provided by the AMA RUC, the Medicare Payment Advisory Commission (MedPAC), and other public commenters.

For many years, the AMA RUC has provided CMS with recommendations on the appropriate relative values for PFS services. Over the past several years, CMS and the AMA RUC have identified and reviewed a number of potentially misvalued codes on an annual basis, based on various identification screens for codes at risk for being misvalued. This annual review of work RVUs and direct PE inputs for potentially misvalued codes was further bolstered by the Affordable Care Act mandate to examine potentially misvalued codes, with an emphasis on the following categories specified in section 1848(c)(2)(K)(ii) of the Act (as added by section 3134 of the Affordable Care Act):

- Codes and families of codes for which there has been the fastest growth.
- Codes or families of codes that have experienced substantial changes in practice expenses.
- Codes that are recently established for new technologies or services.
- Multiple codes that are frequently billed in conjunction with furnishing a single service.

• Codes with low relative values, particularly those that are often billed multiple times for a single treatment.

- Codes which have not been subject to review since the implementation of the RBRVS (the "Harvard-valued" codes).
 - Other codes determined to be appropriate by the Secretary.

In addition to providing recommendations to CMS for work RVUs, the AMA RUC's Practice Expense Subcommittee reviews, and then the AMA RUC recommends, direct PE inputs (clinical labor, disposable supplies, and medical equipment) for individual services. To guide the establishment of malpractice RVUs for new and revised codes before each Five-Year Review of Malpractice, the AMA RUC also provides malpractice crosswalk recommendations, that is, "source" codes with a similar specialty mix of practitioners furnishing the source code and the new/revised code.

CMS reviews the AMA RUC recommendations on a code-by-code basis. For AMA RUC recommendations regarding physician work RVUs, after conducting a clinical review of the codes, we determine whether we agree with the recommended work RVUs for a service (that is, whether we agree the AMA RUC recommended valuation is accurate). If we disagree, we determine an alternative value that better reflects our estimate of the physician work for the service.

Because of the timing of the CPT Editorial Panel decisions, the AMA RUC recommendations, and our rulemaking cycle, we publish these work RVUs in the PFS final rule with comment period as interim final values, subject to public comment. Similarly, we assess the AMA RUC's recommendations for direct PE inputs and malpractice crosswalks, and establish interim final direct PE inputs and malpractice RVUs, which are also subject to comment. We note that the main aspect of our PE valuation that is open for public comment for a new, revised, or potentially misvalued code is the direct PE inputs and not the other elements of the PE valuation methodology, such as the indirect cost allocation methodology, that also contribute to establishing the PE RVUs for a code. The public comment period on the PFS final rule with comment period remains open for 60 days after the rule is issued.

In the interval between closure of the comment period and the subsequent year's PFS final rule with comment period, we consider all of the public comments on the interim final work, PE, and malpractice RVUs for the new, revised, and potentially misvalued codes and the results of the refinement panel, if applicable. Finally, we address the interim final work and malpractice RVUs and interim final direct PE inputs by providing a summary of the public comments and our responses to those comments, including a discussion of any changes to the interim final work or malpractice RVUs or direct PE inputs, in the following year's PFS final rule with comment period. We then typically finalize the direct PE inputs and the work, PE, and malpractice RVUs for the service in that year's PFS final rule with comment period, unless we determine it would be more appropriate to continue their interim final status for another year and solicit further public comment.

1. Methodology

We conducted a review of each code identified in this section and reviewed the current work RVU, if one exists, the AMA RUC-recommended work RVUs, intensity, and time to furnish the preservice, intraservice, and postservice activities, as well as other components of the service that contribute to the value. Our review generally includes, but is not limited to, a review of information provided by the AMA RUC, Health Care Professionals Advisory Committee (HCPAC), and other public commenters, medical literature, and comparative databases, as well as a comparison with other codes within the Medicare PFS, consultation with other physicians and health care professionals within CMS and the federal government. We also assessed the methodology and data used to develop the recommendations submitted to us by the AMA RUC and other public commenters and the rationale for the recommendations. As we noted in the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329), there are a variety of methodologies and approaches used to develop work RVUs, including survey data, building blocks, crosswalk to key reference or similar codes, and magnitude estimation. When referring to a survey, unless otherwise noted, we mean the surveys conducted by specialty societies as part of the formal AMA RUC process. The building block methodology is used to construct, or deconstruct, the work RVU for a CPT code based on component pieces of the code.

Components used in the building block approach may include preservice, intraservice, or postservice time and post-procedure visits. When referring to a bundled CPT code, the components could be the CPT codes that make up the bundled code. Magnitude estimation refers to a methodology for valuing physician work that determines the appropriate work RVU for a service by gauging the total amount of physician work for that service relative to the physician work for similar service across the physician fee schedule without explicitly valuing the components of that work.

The PFS incorporates cross-specialty and cross-organ system relativity. Valuing services requires an assessment of relative value and takes into account the clinical intensity and time required to furnish a service. In selecting which methodological approach will best determine the appropriate value for a service, we consider the current and recommended work and time values, as well as the intensity of the service, all relative to other services.

Several years ago, to aid in the development of preservice time recommendations for new and revised CPT codes, the AMA RUC created standardized preservice time packages. The packages include preservice evaluation time, preservice positioning time, and preservice scrub, dress and wait time. Currently there are six preservice time packages for services typically furnished in the facility setting, reflecting the different combinations of straightforward or difficult procedure, straightforward or difficult patient, and without or with sedation/anesthesia. Currently there are two preservice time packages for services typically furnished in the nonfacility setting, reflecting procedures without and with sedation/anesthesia care.

We have developed several standard building block methodologies to appropriately value services when they have common billing patterns. In cases where a service is typically furnished to a beneficiary on the same day as an evaluation and management (E/M) service, we believe that there is overlap between the two services in some of the activities furnished during the preservice evaluation and postservice time. We believe that at least one-third of the physician time in both the preservice evaluation and postservice period is duplicative of work furnished during the E/M visit. Accordingly, in cases where we believe that the AMA RUC has not adequately accounted for the overlapping activities in the

recommended work RVU and/or times, we adjust the work RVU and/or times to account for the overlap. The work RVU for a service is the product of the time involved in furnishing the service times the intensity of the work. Preservice evaluation time and postservice time both have a long-established intensity of work per unit of time (IWPUT) of 0.0224, which means that 1 minute of preservice evaluation or postservice time equates to 0.0224 of a work RVU. Therefore, in many cases when we remove 2 minutes of preservice time and 2 minutes of postservice time from a procedure to account for the overlap with the same day E/M service, we also remove a work RVU of 0.09 (4 minutes × 0.0224 IWPUT) if we do not believe the overlap in time has already been accounted for in the work RVU. We continue to believe this adjustment is appropriate. The AMA RUC has recognized this valuation policy and, in many cases, addresses the overlap in time and work when a service is typically provided on the same day as an E/M service.

2. Responding to CY 2013 Interim Final RVUs and CY 2014 Proposed RVUs

In this section, we address the interim final values published in the CY 2013 PFS final rule with comment period, as subsequently corrected in the correction notice (78 FR 48996), and the proposed values published in the CY 2014 PFS proposed rule. We discuss the results of the CY 2013 refinement panel for CY 2013 interim final codes the panel reviewed, respond to public comments received on specific interim final and proposed RVUs and direct PE inputs, and address the other new, revised, or potentially misvalued codes with interim final or proposed values. The direct PE inputs are listed in a file called "CY 2014 PFS Direct PE Inputs," available on the CMS website under downloads for the CY 2014 PFS final rule with comment period at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html. The final CY 2014 work, PE, and malpractice RVUs are in Addendum B of a file called "CY 2014 PFS Addenda," available on the CMS website under downloads for the CY 2014 PFS final rule with comment period at http://www.cms.gov/Medicare/Medicare-Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.

(a) Finalizing CY 2013 Interim Final Work RVUs for CY 2014

(i) Refinement Panel

(1) Refinement Panel Process

As discussed in the 1993 PFS final rule with comment period (57 FR 55938), we adopted a refinement panel process to assist us in reviewing the public comments on CPT codes with interim final work RVUs for a year and in developing final work values for the subsequent year. We decided the panel would be comprised of a multispecialty group of physicians who would review and discuss the work involved in each procedure under review, and then each panel member would individually rate the work of the procedure. We believed establishing the panel with a multispecialty group would balance the interests of the specialty societies who commented on the work RVUs with the budgetary and redistributive effects that could occur if we accepted extensive increases in work RVUs across a broad range of services. Depending on the number and range of codes that are subject to refinement in a given year, we establish refinement panels with representatives from four groups of physicians: Clinicians representing the specialty identified with the procedures in question; physicians with practices in related specialties; primary care physicians; and contractor medical directors (CMDs). Typical panels have included 8 to 10 physicians across the four groups.

Following the addition of section 1848(c)(2)(K) to the Act by Section 3134 of the Affordable Care Act, which required the Secretary periodically to review potentially misvalued codes and make appropriate adjustments to the RVUs, we reassessed the refinement panel process. As detailed in the CY 2011 PFS final rule with comment period (75 FR 73306), we believed that the refinement panel process may provide an opportunity to review and discuss the proposed and interim final work RVUs with a clinically diverse group of experts, who then provide informed recommendations. Therefore, we indicated that we would continue the refinement process, but with administrative modification and clarification. We also noted that we would continue using the established composition that includes representatives from the four groups of physicians – clinicians representing the specialty identified with the procedures in question, physicians with practices in related specialties, primary care physicians, and CMDs.

At that time, we made a change in how we calculated refinement panel results. The basis of the refinement panel process is that, following discussion of the information but without an attempt to reach a consensus, each member of the panel submits an independent rating to CMS. Historically, the refinement panel's recommendation to change a work value or to retain the interim final value had hinged solely on the outcome of a statistical test on the ratings (an F-test of panel ratings among the groups of participants). Over time, we found the statistical test used to evaluate the RVU ratings of individual panel members became less reliable as the physicians in each group tended to select a previously discussed value, rather than developing a unique value, thereby reducing the observed variability needed to conduct a robust statistical test. In addition, reliance on values developed using the F-test also occasionally resulted in rank order anomalies among services (that is, a more complex procedure is assigned lower RVUs than a less complex procedure). As a result, we eliminated the use of the statistical F-test and instead used the median work value of the individual panel members' ratings. We said that this approach would simplify the refinement process administratively, while providing a result that reflects the summary opinion of the panel members based on a commonly used measure of central tendency that is not significantly affected by outlier values.

At the same time, we clarified that we have the final authority to set the work RVUs, including making adjustments to the work RVUs resulting from the refinement process, and that we will make such adjustments if warranted by policy concerns (75 FR 73307).

As we continue to strive to make the refinement panel process as effective and efficient as possible, we would like to remind readers that the refinement panels are not intended to review every code for which we did not accept the AMA RUC-recommended work RVUs. Rather, the refinement panels are designed for situations where there is new information available that might provide a reason for a change in work values and for which a multispecialty panel of physicians might provide input that would assist us in making work RVU decisions. To facilitate the selection of services for the refinement panels, we would like to remind specialty societies seeking reconsideration of interim final work RVUs, including consideration by a refinement panel, to specifically state in their public comments that they are

requesting refinement panel review. Furthermore, we have asked commenters requesting refinement panel review to submit sufficient new information concerning the clinical aspects of the work assigned for a service to indicate that referral to the refinement panel is warranted (57 FR 55917).

We note that most of the information presented during the last several refinement panel discussions has been duplicative of the information provided to the AMA RUC during its development of recommendations. As detailed in section II.E.1. of this final rule with comment period, we consider information and recommendations from the AMA RUC when assigning proposed and interim final RVUs to services. Thus, if the only information that a commenter has to present is information already considered by the AMA RUC, referral to a refinement panel is not appropriate. To facilitate selection of codes for refinement, we request that commenters seeking refinement panel review of work RVUs submit supporting information that has not already been considered the AMA RUC in creating recommended work RVUs or by CMS in assigning proposed and interim final work RVUs. We can make best use of our resources as well as those of the specialties involved and physician volunteers by avoiding duplicative consideration of information by the AMA RUC, CMS, and a refinement panel. To achieve this goal, CMS will continue to critically evaluate the need to refer codes to refinement panels in future years, specifically considering any new information provided by commenters.

(2) CY 2013 Interim Final Work RVUs Considered by the Refinement Panel

We referred to the CY 2013 refinement panel 12 CPT codes with CY 2013 interim final work values for which we received a request for refinement that met the requirements described above. For these 12 CPT codes, all commenters requested increased work RVUs. For ease of discussion, we will be referring to these services as "refinement codes." Consistent with the process described above, we convened a multi-specialty panel of physicians to assist us in the review of the information submitted to support increased work RVUs. The panel was moderated by our physician advisors, and consisted of the following voting members:

• One to two clinicians representing the commenting organization.

• One to two primary care clinicians nominated by the American Academy of Family Physicians and the American College of Physicians.

- Four Contractor Medical Directors (CMDs).
- One to two clinicians with practices in related specialties, who were expected to have knowledge of the services under review.

The panel process was designed to capture each participant's independent judgment and his or her clinical experience which informed and drove the discussion of the refinement code during the refinement panel proceedings. Following the discussion, each voting participant rated the physician work of the refinement code and submitted those ratings to CMS directly and confidentially. We note that not all voting participants voted for every CPT code. There was no attempt to achieve consensus among the panel members. As finalized in the CY 2011 PFS final rule with comment period (75 FR 73307), we calculated the median value for each service based upon the individual ratings that were submitted to CMS by panel participants.

Table 23 presents information on the work RVUs for the codes considered by the refinement panel, including the refinement panel ratings and the final CY 2014 work RVUs. In section II.E.2.a.ii., we discuss each of the individual codes reviewed by the refinement panel.

Table 23: Codes Reviewed by the 2013 Multi-Specialty Refinement Panel

HCPCS Code	Short Descriptor	CY 2013 Interim Final Work RVU	AMA RUC/HCPAC Recommended Work RVU	Refinement Panel Median Rating	CY 2014 Work RVU
35475	Angioplasty, arterial	5.75	6.60	6.60	6.60
35476	Angioplasty, venous	4.71	5.10	5.10	5.10
93655	Arrhythmia ablation addon	7.50	9.00	9.00	7.50
93657	Afibablation add-on	7.50	10.00	10.00	7.50
95886	EMG extremity add-on	0.70	0.92	0.92	0.86
95887	EMG non-extremity add- on	0.47	0.73	0.73	0.71
95908	Nerve conduction studies; 3-4 studies	1.25	1.37	1.37	1.25

95909	Nerve conduction studies; 5-6 studies	1.50	1.77	1.77	1.50
95910	Nerve conduction studies; 7-8 studies	2.00	2.80	2.80	2.00
95911	Nerve conduction studies; 9-10 studies	2.50	3.34	3.34	2.50
92912	Nerve conduction studies; 11-12 studies	3.00	4.00	4.00	3.00
95913	Nerve conduction studies; 13 or more studies	3.56	4.20	4.20	3.56

(ii)Code-Specific Issues

Table 24 of this final rule with comment period lists all codes that had a CY 2013 interim final work value. This chart provides the CY 2013 work RVUs, the CY 2014 work RVUs and indicates whether we are finalizing the CY 2014 work RVUs. If there is no work RVUs listed, a letter indicates the relevant PFS procedure status indicator. A list of the PFS procedure status indicators can be found in Addendum A. If the CY 2014 Action column indicates that the CY 2014 values are interim final, public comments on these values will be accepted during the public comment period on this final rule with comment period. The comprehensive list of all CY 2014 RVUs is in Addendum B to this final rule with comment period, which is contained in the "CY 2014 PFS Addenda" available on the CMS website under downloads for the CY 2014 PFS final rule with comment period at <a href="http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-http://www.cms.gov/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-http://www.cms.gov/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-http://www.cms.gov/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-http://www.cms.gov/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-http://www.cms.gov/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-http://www.cms.gov/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-http://www.cms.gov/Medicare-Fee-for-Service-Payme

Regulation-Notices.html. The comprehensive list of all CY 2013 values is in Addendum B to the CY 2013 Correction Notice which is contained in the "CMS-1590-CN Addenda," available on the CMS website under downloads for the CY 2013 correction notice at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html. The time values for all codes are listed in a file called "CY 2014 PFS Physician Time," available on the CMS website under downloads for the CY 2014 PFS final rule with comment period at

http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.

TABLE 24: Codes with CY 2013 Interim Final Work Values

HCPCS Code	Long Descriptor	CY 2013 Work RVU	CY 2014 Work RVU	CY 2014 Action
10120	Incision and removal of foreign body, subcutaneous tissues; simple	1.22	1.22	Finalize
11055	Paring or cutting of benign hyperkeratotic lesion (eg, corn or callus); single lesion	0.35	0.35	Finalize
11056	Paring or cutting of benign hyperkeratotic lesion (eg, corn or callus); 2 to 4 lesions	0.50	0.50	Finalize
11057	Paring or cutting of benign hyperkeratotic lesion (eg, corn or callus); more than 4 lesions	0.65	0.65	Finalize
11300	Shaving of epidermal or dermal lesion, single lesion, trunk, arms or legs; lesion diameter 0.5 cm or less	0.60	0.60	Finalize
11301	Shaving of epidermal or dermal lesion, single lesion, trunk, arms or legs; lesion diameter 0.6 to 1.0 cm	0.90	0.90	Finalize
11302	Shaving of epidermal or dermal lesion, single lesion, trunk, arms or legs; lesion diameter 1.1 to 2.0 cm	1.05	1.05	Finalize
11303	Shaving of epidermal or dermal lesion, single lesion, trunk, arms or legs; lesion diameter over 2.0 cm	1.25	1.25	Finalize
11305	Shaving of epidermal or dermal lesion, single lesion, scalp, neck, hands, feet, genitalia; lesion diameter 0.5 cm or less	0.80	0.80	Finalize
11306	Shaving of epidermal or dermal lesion, single lesion, scalp, neck, hands, feet, genitalia; lesion diameter 0.6 to 1.0 cm	0.96	0.96	Finalize
11307	Shaving of epidermal or dermal lesion, single lesion, scalp, neck, hands, feet, genitalia; lesion diameter 1.1 to 2.0 cm	1.20	1.20	Finalize
11308	Shaving of epidermal or dermal lesion, single lesion, scalp, neck, hands, feet, genitalia; lesion diameter over 2.0 cm	1.46	1.46	Finalize
11310	Shaving of epidermal or dermal lesion, single lesion, face, ears, eyelids, nose, lips, mucous membrane; lesion diameter 0.5 cm or less	0.80	0.80	Finalize
11311	Shaving of epidermal or dermal lesion, single lesion, face, ears, eyelids, nose, lips, mucous membrane; lesion diameter 0.6 to 1.0 cm	1.10	1.10	Finalize
11312	Shaving of epidermal or dermal lesion, single lesion, face, ears, eyelids, nose, lips, mucous membrane; lesion diameter 1.1 to 2.0 cm	1.30	1.30	Finalize

HCPCS Code	Long Descriptor	CY 2013 Work RVU	CY 2014 Work RVU	CY 2014 Action
11313	Shaving of epidermal or dermal lesion, single lesion, face, ears, eyelids, nose, lips, mucous membrane; lesion diameter over 2.0 cm	1.68	1.68	Finalize
11719	Trimming of nondystrophic nails, any number	0.17	0.17	Finalize
12035	Repair, intermediate, wounds of scalp, axillae, trunk and/ or extremities (excluding hands and feet); 12.6 cm to 20.0 cm	3.50	3.50	Finalize
12036	Repair, intermediate, wounds of scalp, axillae, trunk and/ or extremities (excluding hands and feet); 20.1 cm to 30.0 cm	4.23	4.23	Finalize
12037	Repair, intermediate, wounds of scalp, axillae, trunk and/ or extremities (excluding hands and feet); over 30.0 cm	5.00	5.00	Finalize
12045	Repair, intermediate, wounds of neck, hands, feet and/or external genitalia; 12.6 cm to 20.0 cm	3.75	3.75	Finalize
12046	Repair, intermediate, wounds of neck, hands, feet and/or external genitalia; 20.1 cm to 30.0 cm	4.30	4.30	Finalize
12047	Repair, intermediate, wounds of neck, hands, feet and/or external genitalia; over 30.0 cm	4.95	4.95	Finalize
12055	Repair, intermediate, wounds of face, ears, eyelids, nose, lips and/or mucous membranes; 12.6 cm to 20.0 cm	4.50	4.50	Finalize
12056	Repair, intermediate, wounds of face, ears, eyelids, nose, lips and/or mucous membranes; 20.1 cm to 30.0 cm	5.30	5.30	Finalize
12057	Repair, intermediate, wounds of face, ears, eyelids, nose, lips and/or mucous membranes; over 30.0 cm	6.00	6.00	Finalize
13100	Repair, complex, trunk; 1.1 cm to 2.5 cm	3.00	3.00	Finalize
13101	Repair, complex, trunk; 2.6 cm to 7.5 cm	3.50	3.50	Finalize
13102	Repair, complex, trunk; each additional 5 cm or less (list separately in addition to code for primary procedure)	1.24	1.24	Finalize
13120	Repair, complex, scalp, arms, and/or legs; 1.1 cm to 2.5 cm	3.23	3.23	Finalize
13121	Repair, complex, scalp, arms, and/or legs; 2.6 cm to 7.5 cm	4.00	4.00	Finalize
13122	Repair, complex, scalp, arms, and/or legs; each additional 5 cm or less (list separately in addition to code for primary procedure)	1.44	1.44	Finalize
13131	Repair, complex, forehead, cheeks, chin, mouth, neck, axillae, genitalia, hands and/or feet; 1.1 cm to 2.5 cm	3.73	3.73	Finalize
13132	Repair, complex, forehead, cheeks, chin, mouth, neck, axillae, genitalia, hands and/or feet; 2.6 cm to 7.5 cm	4.78	4.78	Finalize

HCPCS Code	Long Descriptor	CY 2013 Work RVU	CY 2014 Work RVU	CY 2014 Action
13133	Repair, complex, forehead, cheeks, chin, mouth, neck, axillae, genitalia, hands and/or feet; each additional 5 cm or less (list separately in addition to code for primary procedure)	2.19	2.19	Finalize
13150	Repair, complex, eyelids, nose, ears and/or lips; 1.0 cm or less	3.58	D	D
13151	Repair, complex, eyelids, nose, ears and/or lips; 1.1 cm to 2.5 cm	4.34	4.34	Finalize
13152	Repair, complex, eyelids, nose, ears and/or lips; 2.6 cm to 7.5 cm	4.90	5.34	Finalize
13153	Repair, complex, eyelids, nose, ears and/or lips; each additional 5 cm or less (list separately in addition to code for primary procedure)	2.38	2.38	Finalize
20985	Computer-assisted surgical navigational procedure for musculoskeletal procedures, image-less (list separately in addition to code for primary procedure)	2.50	2.50	Finalize
22586	Arthrodesis, pre-sacral interbody technique, including disc space preparation, discectomy, with posterior instrumentation, with image guidance, includes bone graft when performed, 15-s1 interspace	28.12	28.12	Finalize
23350	Injection procedure for shoulder arthrography or enhanced ct/mri shoulder arthrography	1.00	1.00	Finalize
23331	Removal of foreign body, shoulder; deep (eg, neer hemiarthroplasty removal)	7.63	D	D
23332	Removal of foreign body, shoulder; complicated (eg, total shoulder)	12.37	D	D
23472	Arthroplasty, glenohumeral joint; total shoulder (glenoid and proximal humeral replacement (eg, total shoulder))	22.13	22.13	Finalize
23473	Revision of total shoulder arthroplasty, including allograft when performed; humeral or glenoid component	25.00	25.00	Finalize
23474	Revision of total shoulder arthroplasty, including allograft when performed; humeral and glenoid component	27.21	27.21	Finalize
23600	Closed treatment of proximal humeral (surgical or anatomical neck) fracture; without manipulation	3.00	3.00	Interim Final
24160	Implant removal; elbow joint	8.00	18.63	Interim Final

HCPCS Code	Long Descriptor	CY 2013 Work RVU	CY 2014 Work RVU	CY 2014 Action
24363	Arthroplasty, elbow; with distal humerus and proximal ulnar prosthetic replacement (eg, total elbow)	22.00	22.00	Finalize
24370	Revision of total elbow arthroplasty, including allograft when performed; humeral or ulnar component	23.55	23.55	Finalize
24371	Revision of total elbow arthroplasty, including allograft when performed; humeral and ulnar component	27.50	27.50	Finalize
28470	Closed treatment of metatarsal fracture; without manipulation, each	2.03	2.03	Interim Final
29075	Application, cast; elbow to finger (short arm)	0.77	0.77	Interim Final
29581	Application of multi-layer compression system; leg (below knee), including ankle and foot	0.25	0.25	Interim Final
29582	Application of multi-layer compression system; thigh and leg, including ankle and foot, when performed	0.35	0.35	Interim Final
29583	Application of multi-layer compression system; upper arm and forearm	0.25	0.25	Interim Final
29584	Application of multi-layer compression system; upper arm, forearm, hand, and fingers	0.35	0.35	Interim Final
29824	Arthroscopy, shoulder, surgical; distal claviculectomy including distal articular surface (mumford procedure)	8.98	8.98	Interim Final
29826	Arthroscopy, shoulder, surgical; decompression of subacromial space with partial acromioplasty, with coracoacromial ligament (ie, arch) release, when performed (list separately in addition to code for primary procedure)	3.00	3.00	Interim Final
29827	Arthroscopy, shoulder, surgical; with rotator cuff repair	15.59	15.59	Finalize
29828	Arthroscopy, shoulder, surgical; biceps tenodesis	13.16	13.16	Finalize
31231	Nasal endoscopy, diagnostic, unilateral or bilateral (separate procedure)	1.10	1.10	Finalize
31647	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with balloon occlusion, when performed, assessment of air leak, airway sizing, and insertion of bronchial valve(s), initial lobe	4.40	4.40	Finalize
31648	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with removal of bronchial valve(s), initial lobe	4.20	4.20	Finalize

HCPCS Code	Long Descriptor	CY 2013 Work RVU	CY 2014 Work RVU	CY 2014 Action
31649	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with removal of bronchial valve(s), each additional lobe (list separately in addition to code for primary procedure)	1.44	1.44	Finalize
31651	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with balloon occlusion, when performed, assessment of air leak, airway sizing, and insertion of bronchial valve(s), each additional lobe (list separately in addition to code for primary procedure[s])	1.58	1.58	Finalize
31660	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, 1 lobe	4.25	4.25	Finalize
31661	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, 2 or more lobes	4.50	4.50	Finalize
32440	Removal of lung, pneumonectomy;	27.28	27.28	Finalize
32480	Removal of lung, other than pneumonectomy; single lobe (lobectomy)	25.82	25.82	Finalize
32482	Removal of lung, other than pneumonectomy; 2 lobes (bilobectomy)	27.44	27.44	Finalize
32491	Removal of lung, other than pneumonectomy; with resection-plication of emphysematous lung(s) (bullous or non-bullous) for lung volume reduction, sternal split or transthoracic approach, includes any pleural procedure, when performed	25.24	25.24	Finalize
32551	Tube thoracostomy, includes connection to drainage system (eg, water seal), when performed, open (separate procedure)	3.29	3.29	Finalize
32554	Thoracentesis, needle or catheter, aspiration of the pleural space; without imaging guidance	1.82	1.82	Finalize
32555	Thoracentesis, needle or catheter, aspiration of the pleural space; with imaging guidance	2.27	2.27	Finalize
32556	Pleural drainage, percutaneous, with insertion of indwelling catheter; without imaging guidance	2.50	2.50	Finalize
32557	Pleural drainage, percutaneous, with insertion of indwelling catheter; with imaging guidance	3.12	3.12	Finalize
32663	Thoracoscopy, surgical; with lobectomy (single lobe)	24.64	24.64	Finalize

HCPCS Code	Long Descriptor	CY 2013 Work RVU	CY 2014 Work RVU	CY 2014 Action
32668	Thoracoscopy, surgical; with diagnostic wedge resection followed by anatomic lung resection (list separately in addition to code for primary procedure)	3.00	3.00	Finalize
32669	Thoracoscopy, surgical; with removal of a single lung segment (segmentectomy)	23.53	23.53	Finalize
32670	Thoracoscopy, surgical; with removal of two lobes (bilobectomy)	28.52	28.52	Finalize
32671	Thoracoscopy, surgical; with removal of lung (pneumonectomy)	31.92	31.92	Finalize
32672	Thoracoscopy, surgical; with resection-plication for emphysematous lung (bullous or non-bullous) for lung volume reduction (lvrs), unilateral includes any pleural procedure, when performed	27.00	27.00	Finalize
32673	Thoracoscopy, surgical; with resection of thymus, unilateral or bilateral	21.13	21.13	Finalize
32701	Thoracic target(s) delineation for stereotactic body radiation therapy (srs/sbrt), (photon or particle beam), entire course of treatment	4.18	4.18	Finalize
33361	Transcatheter aortic valve replacement (tavr/tavi) with prosthetic valve; percutaneous femoral artery approach	25.13	25.13	Finalize
33362	Transcatheter aortic valve replacement (tavr/tavi) with prosthetic valve; open femoral artery approach	27.52	27.52	Finalize
33363	Transcatheter aortic valve replacement (tavr/tavi) with prosthetic valve; open axillary artery approach	28.50	28.50	Finalize
33364	Transcatheter aortic valve replacement (tavr/tavi) with prosthetic valve; open iliac artery approach	30.00	30.00	Finalize
33365	Transcatheter aortic valve replacement (tavr/tavi) with prosthetic valve; transaortic approach (eg, median sternotomy, mediastinotomy)	33.12	33.12	Finalize
33367	Transcatheter aortic valve replacement (tavr/tavi) with prosthetic valve; cardiopulmonary bypass support with percutaneous peripheral arterial and venous cannulation (eg, femoral vessels) (list separately in addition to code for primary procedure)	11.88	11.88	Finalize

HCPCS Code	Long Descriptor	CY 2013 Work RVU	CY 2014 Work RVU	CY 2014 Action
33368	Transcatheter aortic valve replacement (tavr/tavi) with prosthetic valve; cardiopulmonary bypass support with open peripheral arterial and venous cannulation (eg, femoral, iliac, axillary vessels) (list separately in addition to code for primary procedure)	14.39	14.39	Finalize
33369	Transcatheter aortic valve replacement (tavr/tavi) with prosthetic valve; cardiopulmonary bypass support with central arterial and venous cannulation (eg, aorta, right atrium, pulmonary artery) (list separately in addition to code for primary procedure)	19.00	19.00	Finalize
33405	Replacement, aortic valve, with cardiopulmonary bypass; with prosthetic valve other than homograft or stentless valve	41.32	41.32	Finalize
33430	Replacement, mitral valve, with cardiopulmonary bypass	50.93	50.93	Finalize
33533	Coronary artery bypass, using arterial graft(s); single arterial graft	33.75	33.75	Finalize
33990	Insertion of ventricular assist device, percutaneous including radiological supervision and interpretation; arterial access only	8.15	8.15	Finalize
33991	Insertion of ventricular assist device, percutaneous including radiological supervision and interpretation; both arterial and venous access, with transseptal puncture	11.88	11.88	Finalize
33992	Removal of percutaneous ventricular assist device at separate and distinct session from insertion	4.00	4.00	Finalize
33993	Repositioning of percutaneous ventricular assist device with imaging guidance at separate and distinct session from insertion	3.51	3.51	Finalize
35475	Transluminal balloon angioplasty, percutaneous; brachiocephalic trunk or branches, each vessel	5.75	6.60	Finalize
35476	Transluminal balloon angioplasty, percutaneous; venous	4.71	5.10	Finalize
36221	Non-selective catheter placement, thoracic aorta, with angiography of the extracranial carotid, vertebral, and/or intracranial vessels, unilateral or bilateral, and all associated radiological supervision and interpretation, includes angiography of the cervicocerebral arch, when performed	4.17	4.17	Finalize

HCPCS Code	Long Descriptor	CY 2013 Work RVU	CY 2014 Work RVU	CY 2014 Action
36222	Selective catheter placement, common carotid or innominate artery, unilateral, any approach, with angiography of the ipsilateral extracranial carotid circulation and all associated radiological supervision and interpretation, includes angiography of the cervicocerebral arch, when performed	5.53	5.53	Finalize
36223	Selective catheter placement, common carotid or innominate artery, unilateral, any approach, with angiography of the ipsilateral intracranial carotid circulation and all associated radiological supervision and interpretation, includes angiography of the extracranial carotid and cervicocerebral arch, when performed	6.00	6.00	Finalize
36224	Selective catheter placement, internal carotid artery, unilateral, with angiography of the ipsilateral intracranial carotid circulation and all associated radiological supervision and interpretation, includes angiography of the extracranial carotid and cervicocerebral arch, when performed	6.50	6.50	Finalize
36225	Selective catheter placement, subclavian or innominate artery, unilateral, with angiography of the ipsilateral vertebral circulation and all associated radiological supervision and interpretation, includes angiography of the cervicocerebral arch, when performed	6.00	6.00	Finalize
36226	Selective catheter placement, vertebral artery, unilateral, with angiography of the ipsilateral vertebral circulation and all associated radiological supervision and interpretation, includes angiography of the cervicocerebral arch, when performed	6.50	6.50	Finalize
36227	Selective catheter placement, external carotid artery, unilateral, with angiography of the ipsilateral external carotid circulation and all associated radiological supervision and interpretation (list separately in addition to code for primary procedure)	2.09	2.09	Finalize
36228	Selective catheter placement, each intracranial branch of the internal carotid or vertebral arteries, unilateral, with angiography of the selected vessel circulation and all associated radiological supervision and interpretation (eg, middle cerebral artery, posterior inferior cerebellar artery) (list separately in addition to code for primary procedure)	4.25	4.25	Finalize

HCPCS Code	Long Descriptor	CY 2013 Work RVU	CY 2014 Work RVU	CY 2014 Action
37197	Transcatheter retrieval, percutaneous, of intravascular foreign body (eg, fractured venous or arterial catheter), includes radiological supervision and interpretation, and imaging guidance (ultrasound or fluoroscopy), when performed	6.29	6.29	Finalize
37211	Transcatheter therapy, arterial infusion for thrombolysis other than coronary, any method, including radiological supervision and interpretation, initial treatment day	8.00	8.00	Finalize
37212	Transcatheter therapy, venous infusion for thrombolysis, any method, including radiological supervision and interpretation, initial treatment day	7.06	7.06	Finalize
37213	Transcatheter therapy, arterial or venous infusion for thrombolysis other than coronary, any method, including radiological supervision and interpretation, continued treatment on subsequent day during course of thrombolytic therapy, including follow-up catheter contrast injection, position change, or exchange, when performed;	5.00	5.00	Finalize
37214	Transcatheter therapy, arterial or venous infusion for thrombolysis other than coronary, any method, including radiological supervision and interpretation, continued treatment on subsequent day during course of thrombolytic therapy, including follow-up catheter contrast injection, position change, or exchange, when performed;	2.74	2.74	Finalize
38240	Hematopoietic progenitor cell (hpc); allogeneic transplantation per donor	3.00	4.00	Finalize
38241	Hematopoietic progenitor cell (hpc); autologous transplantation	3.00	3.00	Finalize
38242	Allogeneic lymphocyte infusions	2.11	2.11	Finalize
38243	Hematopoietic progenitor cell (hpc); hpc boost	2.13	2.13	Finalize
40490	Biopsy of lip	1.22	1.22	Finalize
43206	Esophagoscopy, rigid or flexible; with optical endomicroscopy	С	2.39	Interim Final
43252	Upper gastrointestinal endoscopy including esophagus, stomach, and either the duodenum and/or jejunum as appropriate; with optical endomicroscopy	С	3.06	Interim Final
44705	Preparation of fecal microbiota for instillation, including assessment of donor specimen	Ι	I	Finalize

HCPCS Code	Long Descriptor	CY 2013 Work RVU	CY 2014 Work RVU	CY 2014 Action
45330	Sigmoidoscopy, flexible; diagnostic, with or without collection of specimen(s) by brushing or washing (separate procedure)	0.96	0.96	Finalize
47562	Laparoscopy, surgical; cholecystectomy	10.47	10.47	Finalize
47563	Laparoscopy, surgical; cholecystectomy with cholangiography	11.47	11.47	Finalize
47600	Cholecystectomy;	17.48	17.48	Finalize
47605	Cholecystectomy; with cholangiography	18.48	18.48	Finalize
49505	Repair initial inguinal hernia, age 5 years or older; reducible	7.96	7.96	Finalize
50590	Lithotripsy, extracorporeal shock wave	9.77	9.77	Finalize
52214	Cystourethroscopy, with fulguration (including cryosurgery or laser surgery) of trigone, bladder neck, prostatic fossa, urethra, or periurethral glands	3.50	3.50	Finalize
52224	Cystourethroscopy, with fulguration (including cryosurgery or laser surgery) or treatment of minor (less than 0.5 cm) lesion(s) with or without biopsy	4.05	4.05	Finalize
52234	Cystourethroscopy, with fulguration (including cryosurgery or laser surgery) and/or resection of; small bladder tumor(s) (0.5 up to 2.0 cm)	4.62	4.62	Finalize
52235	Cystourethroscopy, with fulguration (including cryosurgery or laser surgery) and/or resection of; medium bladder tumor(s) (2.0 to 5.0 cm)	5.44	5.44	Finalize
52240	Cystourethroscopy, with fulguration (including cryosurgery or laser surgery) and/or resection of; large bladder tumor(s)	7.50	7.50	Finalize
52287	Cystourethroscopy, with injection(s) for chemodenervation of the bladder	3.20	3.20	Finalize
52351	Cystourethroscopy, with ureteroscopy and/or pyeloscopy; diagnostic	5.75	5.75	Finalize
52352	Cystourethroscopy, with ureteroscopy and/or pyeloscopy; with removal or manipulation of calculus (ureteral catheterization is included)	6.75	6.75	Finalize
52353	Cystourethroscopy, with ureteroscopy and/or pyeloscopy; with lithotripsy (ureteral catheterization is included)	7.50	7.50	Finalize
52354	Cystourethroscopy, with ureteroscopy and/or pyeloscopy; with biopsy and/or fulguration of ureteral or renal pelvic lesion	8.00	8.00	Finalize

HCPCS Code	Long Descriptor	CY 2013 Work RVU	CY 2014 Work RVU	CY 2014 Action
52355	Cystourethroscopy, with ureteroscopy and/or pyeloscopy; with resection of ureteral or renal pelvic tumor	9.00	9.00	Finalize
53850	Transurethral destruction of prostate tissue; by microwave thermotherapy	10.08	10.08	Finalize
60520	Thymectomy, partial or total; transcervical approach (separate procedure)	17.16	17.16	Finalize
60521	Thymectomy, partial or total; sternal split or transthoracic approach, without radical mediastinal dissection (separate procedure)	19.18	19.18	Finalize
60522	Thymectomy, partial or total; sternal split or transthoracic approach, with radical mediastinal dissection (separate procedure)	23.48	23.48	Finalize
64450	Injection, anesthetic agent; other peripheral nerve or branch	0.75	0.75	Finalize
64612	Chemodenervation of muscle(s); muscle(s) innervated by facial nerve, unilateral (eg, for blepharospasm, hemifacial spasm)	1.41	1.41	Finalize
64613	Chemodenervation of muscle(s); neck muscle(s) (eg, for spasmodic torticollis, spasmodic dysphonia)	2.01	D	D
64614	Chemodenervation of muscle(s); extremity and/or trunk muscle(s) (eg, for dystonia, cerebral palsy, multiple sclerosis)	2.20	D	D
64615	Chemodenervation of muscle(s); muscle(s) innervated by facial, trigeminal, cervical spinal and accessory nerves, bilateral (eg, for chronic migraine)	1.85	1.85	Finalize
64640	Destruction by neurolytic agent; other peripheral nerve or branch	1.23	1.23	Finalize
65222	Removal of foreign body, external eye; corneal, with slit lamp	0.84	0.84	Finalize
65800	Paracentesis of anterior chamber of eye (separate procedure); with removal of aqueous	1.53	1.53	Finalize

HCPCS Code	Long Descriptor	CY 2013 Work RVU	CY 2014 Work RVU	CY 2014 Action
66982	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (eg, iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage	11.08	11.08	Finalize
66984	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1 stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification)	8.52	8.52	Finalize
67028	Intravitreal injection of a pharmacologic agent (separate procedure)	1.44	1.44	Finalize
67810	Incisional biopsy of eyelid skin including lid margin	1.18	1.18	Finalize
68200	Subconjunctival injection	0.49	0.49	Finalize
69200	Removal foreign body from external auditory canal; without general anesthesia	0.77	0.77	Finalize
69433	Tympanostomy (requiring insertion of ventilating tube), local or topical anesthesia	1.57	1.57	Finalize
72040	Radiologic examination, spine, cervical; 3 views or less	0.22	0.22	Finalize
72050	Radiologic examination, spine, cervical; 4 or 5 views	0.31	0.31	Finalize
72052	Radiologic examination, spine, cervical; 6 or more views	0.36	0.36	Finalize
72191	Computed tomographic angiography, pelvis, with contrast material(s), including noncontrast images, if performed, and image postprocessing	1.81	1.81	Interim Final
73221	Magnetic resonance (eg, proton) imaging, any joint of upper extremity; without contrast material(s)	1.35	1.35	Finalize
73721	Magnetic resonance (eg, proton) imaging, any joint of lower extremity; without contrast material	1.35	1.35	Finalize
74170	Computed tomography, abdomen; without contrast material, followed by contrast material(s) and further sections	1.40	1.40	Finalize
74174	Computed tomographic angiography, abdomen and pelvis, with contrast material(s), including noncontrast images, if performed, and image postprocessing	2.20	2.20	Finalize

HCPCS Code	Long Descriptor	CY 2013 Work RVU	CY 2014 Work RVU	CY 2014 Action
74175	Computed tomographic angiography, abdomen, with contrast material(s), including noncontrast images, if performed, and image postprocessing	1.90	1.90	Finalize
74247	Radiological examination, gastrointestinal tract, upper, air contrast, with specific high density barium, effervescent agent, with or without glucagon; with or without delayed films, with kub	0.69	0.69	Finalize
74280	Radiologic examination, colon; air contrast with specific high density barium, with or without glucagon	0.99	0.99	Finalize
74400	Urography (pyelography), intravenous, with or without kub, with or without tomography	0.49	0.49	Finalize
75896-26	Transcatheter therapy, infusion, other than for thrombolysis, radiological supervision and interpretation	1.31	1.31	Interim Final
75896-TC	Transcatheter therapy, infusion, other than for thrombolysis, radiological supervision and interpretation	С	С	Interim Final
75898-26	Angiography through existing catheter for follow-up study for transcatheter therapy, embolization or infusion, other than for thrombolysis	1.65	1.65	Interim Final
75898-TC	Angiography through existing catheter for follow-up study for transcatheter therapy, embolization or infusion, other than for thrombolysis	С	С	Interim Final
76830	Ultrasound, transvaginal	0.69	0.69	Finalize
76872	Ultrasound, transrectal;	0.69	0.69	Finalize
77001	Fluoroscopic guidance for central venous access device placement, replacement (catheter only or complete), or removal (includes fluoroscopic guidance for vascular access and catheter manipulation, any necessary contrast injections through access site or catheter with related venography radiologic supervision and interpretation, and radiographic documentation of final catheter position) (list separately in addition to code for primary procedure)	0.38	0.38	Interim Final
77002	Fluoroscopic guidance for needle placement (eg, biopsy, aspiration, injection, localization device)	0.54	0.54	Interim Final
77003	Fluoroscopic guidance and localization of needle or catheter tip for spine or paraspinous diagnostic or therapeutic injection procedures (epidural or subarachnoid)	0.60	0.60	Interim Final

HCPCS Code	Long Descriptor	CY 2013 Work RVU	CY 2014 Work RVU	CY 2014 Action
77080	Dual-energy x-ray absorptiometry (dxa), bone density study, 1 or more sites; axial skeleton (eg, hips, pelvis, spine)	0.20	0.20	Finalize
77082	Dual-energy x-ray absorptiometry (dxa), bone density study, 1 or more sites; vertebral fracture assessment	0.17	0.17	Finalize
77301	Intensity modulated radiotherapy plan, including dose- volume histograms for target and critical structure partial tolerance specifications	7.99	7.99	Finalize
78012	Thyroid uptake, single or multiple quantitative measurement(s) (including stimulation, suppression, or discharge, when performed)	0.19	0.19	Finalize
78013	Thyroid imaging (including vascular flow, when performed);	0.37	0.37	Finalize
78014	Thyroid imaging (including vascular flow, when performed); with single or multiple uptake(s) quantitative measurement(s) (including stimulation, suppression, or discharge, when performed)	0.50	0.50	Finalize
78070	Parathyroid planar imaging (including subtraction, when performed);	0.80	0.80	Finalize
78071	Parathyroid planar imaging (including subtraction, when performed); with tomographic (spect)	1.20	1.20	Finalize
78072	Parathyroid planar imaging (including subtraction, when performed); with tomographic (spect), and concurrently acquired computed tomography (ct) for anatomical localization	1.60	1.60	Finalize
78278	Acute gastrointestinal blood loss imaging	0.99	0.99	Finalize
78472	Cardiac blood pool imaging, gated equilibrium; planar, single study at rest or stress (exercise and/or pharmacologic), wall motion study plus ejection fraction, with or without additional quantitative processing	0.98	0.98	Finalize
86153	Cell enumeration using immunologic selection and identification in fluid specimen (eg, circulating tumor cells in blood); physician interpretation and report, when required	0.69	0.69	Finalize
88120	Cytopathology, in situ hybridization (eg, fish), urinary tract specimen with morphometric analysis, 3-5 molecular probes, each specimen; manual	1.20	1.20	Interim Final
88121	Cytopathology, in situ hybridization (eg, fish), urinary tract specimen with morphometric analysis, 3-5 molecular probes, each specimen; using computer-assisted technology	1.00	1.00	Interim Final

HCPCS	Long Descriptor	CY 2013 Work	CY 2014 Work	CY 2014
Code	Long Descriptor	RVU	RVU	Action
88312	Special stain including interpretation and report; group i for microorganisms (eg, acid fast, methenamine silver)	0.54	0.54	Finalize
88365	In situ hybridization (eg, fish), each probe	1.20	1.20	Interim Final
88367	Morphometric analysis, in situ hybridization (quantitative or semi-quantitative) each probe; using computer-assisted technology	1.30	1.30	Interim Final
88368	Morphometric analysis, in situ hybridization (quantitative or semi-quantitative) each probe; manual	1.40	1.40	Interim Final
88375	Optical endomicroscopic image(s), interpretation and report, real-time or referred, each endoscopic session	С	I	Interim Final
90785	Interactive complexity (list separately in addition to the code for primary procedure)	0.11	0.33	Interim Final
90791	Psychiatric diagnostic evaluation	2.80	3.00	Interim Final
90792	Psychiatric diagnostic evaluation with medical services	2.96	3.25	Interim Final
90832	Psychotherapy, 30 minutes with patient and/or family member	1.25	1.50	Interim Final
90833	Psychotherapy, 30 minutes with patient and/or family member when performed with an evaluation and management service (list separately in addition to the code for primary procedure)	0.98	1.50	Interim Final
90834	Psychotherapy, 45 minutes with patient and/or family member	1.89	2.00	Interim Final
90836	Psychotherapy, 45 minutes with patient and/or family member when performed with an evaluation and management service (list separately in addition to the code for primary procedure)	1.60	1.90	Interim Final
90837	Psychotherapy, 60 minutes with patient and/or family member	2.83	3.00	Interim Final
90838	Psychotherapy, 60 minutes with patient and/or family member when performed with an evaluation and management service (list separately in addition to the code for primary procedure)	2.56	2.50	Interim Final
90839	Psychotherapy for crisis; first 60 minutes	С	3.13	Interim Final

HCPCS Code	Long Descriptor	CY 2013 Work RVU	CY 2014 Work RVU	CY 2014 Action
90840	Psychotherapy for crisis; each additional 30 minutes (list separately in addition to code for primary service)	С	1.50	Interim Final
90845	Psychoanalysis	1.79	2.10	Interim Final
90846	Family psychotherapy (without the patient present)	1.83	2.40	Interim Final
90847	Family psychotherapy (conjoint psychotherapy) (with patient present)	2.21	2.50	Interim Final
90853	Group psychotherapy (other than of a multiple-family group)	0.59	0.59	Interim Final
90863	Pharmacologic management, including prescription and review of medication, when performed with psychotherapy services (list separately in addition to the code for primary procedure)	I	I	Interim Final
91112	Gastrointestinal transit and pressure measurement, stomach through colon, wireless capsule, with interpretation and report	2.10	2.10	Finalize
92083	Visual field examination, unilateral or bilateral, with interpretation and report; extended examination (eg, goldmann visual fields with at least 3 isopters plotted and static determination within the central 30 _i , or quantitative, automated threshold perimetry, octopus program g-1, 32 or 42, humphrey visual field analyzer full threshold programs 30-2, 24-2, or 30/60-2)	0.50	0.50	Finalize
92100	Serial tonometry (separate procedure) with multiple measurements of intraocular pressure over an extended time period with interpretation and report, same day (eg, diurnal curve or medical treatment of acute elevation of intraocular pressure)	0.61	0.61	Finalize
92235	Fluorescein angiography (includes multiframe imaging) with interpretation and report	0.81	0.81	Finalize
92286	Anterior segment imaging with interpretation and report; with specular microscopy and endothelial cell analysis	0.40	0.40	Finalize
92920	Percutaneous transluminal coronary angioplasty; single major coronary artery or branch	10.10	10.10	Finalize
92921	Percutaneous transluminal coronary angioplasty; each additional branch of a major coronary artery (list separately in addition to code for primary procedure)	В	В	Finalize

HCPCS Code	Long Descriptor	CY 2013 Work RVU	CY 2014 Work RVU	CY 2014 Action
92924	Percutaneous transluminal coronary atherectomy, with coronary angioplasty when performed; single major coronary artery or branch	11.99	11.99	Finalize
92925	Percutaneous transluminal coronary atherectomy, with coronary angioplasty when performed; each additional branch of a major coronary artery (list separately in addition to code for primary procedure)	В	В	Finalize
92928	Percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch	11.21	11.21	Finalize
92929	Percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed; each additional branch of a major coronary artery (list separately in addition to code for primary procedure)	В	В	Finalize
92933	Percutaneous transluminal coronary atherectomy, with intracoronary stent, with coronary angioplasty when performed; single major coronary artery or branch	12.54	12.54	Finalize
92934	Percutaneous transluminal coronary atherectomy, with intracoronary stent, with coronary angioplasty when performed; each additional branch of a major coronary artery (list separately in addition to code for primary procedure)	В	В	Finalize
92937	Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of intracoronary stent, atherectomy and angioplasty, including distal protection when performed; single vessel	11.20	11.20	Finalize
92938	Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of intracoronary stent, atherectomy and angioplasty, including distal protection when performed; each additional branch subtended by the bypass graft (list separately in addition to code for primary procedure)	В	В	Finalize

HCPCS Code	Long Descriptor	CY 2013 Work RVU	CY 2014 Work RVU	CY 2014 Action
92941	Percutaneous transluminal revascularization of acute total/ subtotal occlusion during acute myocardial infarction, coronary artery or coronary artery bypass graft, any combination of intracoronary stent, atherectomy and angioplasty, including aspiration thrombectomy when performed, single vessel	12.56	12.56	Finalize
92943	Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of intracoronary stent, atherectomy and angioplasty; single vessel	12.56	12.56	Finalize
92944	Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of intracoronary stent, atherectomy and angioplasty; each additional coronary artery, coronary artery branch, or bypass graft (list separately in addition to code for primary procedure)	В	В	Finalize
93015	Cardiovascular stress test using maximal or submaximal treadmill or bicycle exercise, continuous electrocardiographic monitoring, and/or pharmacological stress; with supervision, interpretation and report	0.75	0.75	Finalize
93016	Cardiovascular stress test using maximal or submaximal treadmill or bicycle exercise, continuous electrocardiographic monitoring, and/or pharmacological stress; supervision only, without interpretation and report	0.45	0.45	Finalize
93018	Cardiovascular stress test using maximal or submaximal treadmill or bicycle exercise, continuous electrocardiographic monitoring, and/or pharmacological stress; interpretation and report only	0.30	0.30	Finalize
93308	Echocardiography, transthoracic, real-time with image documentation (2d), includes m-mode recording, when performed, follow-up or limited study	0.53	0.53	Finalize

HCPCS Code	Long Descriptor	CY 2013 Work RVU	CY 2014 Work RVU	CY 2014 Action
93653	Comprehensive electrophysiologic evaluation including insertion and repositioning of multiple electrode catheters with induction or attempted induction of an arrhythmia with right atrial pacing and recording, right ventricular pacing and recording, his recording with intracardiac catheter ablation of arrhythmogenic focus; with treatment of supraventricular tachycardia by ablation of fast or slow atrioventricular pathway, accessory atrioventricular connection, cavotricuspid isthmus or other single atrial focus or source of atrial re-entry	15.00	15.00	Finalize
93654	Comprehensive electrophysiologic evaluation including insertion and repositioning of multiple electrode catheters with induction or attempted induction of an arrhythmia with right atrial pacing and recording, right ventricular pacing and recording, his recording with intracardiac catheter ablation of arrhythmogenic focus; with treatment of ventricular tachycardia or focus of ventricular ectopy including intracardiac electrophysiologic 3d mapping, when performed, and left ventricular pacing and recording, when performed	20.00	20.00	Finalize
93655	Intracardiac catheter ablation of a discrete mechanism of arrhythmia which is distinct from the primary ablated mechanism, including repeat diagnostic maneuvers, to treat a spontaneous or induced arrhythmia (list separately in addition to code for primary procedure)	7.50	7.50	Finalize
93656	Comprehensive electrophysiologic evaluation including transseptal catheterizations, insertion and repositioning of multiple electrode catheters with induction or attempted induction of an arrhythmia with atrial recording and pacing, when possible, right ventricular pacing and recording, his bundle recording with intracardiac catheter ablation of arrhythmogenic focus, with treatment of atrial fibrillation by ablation by pulmonary vein isolation	20.02	20.02	Finalize
93657	Additional linear or focal intracardiac catheter ablation of the left or right atrium for treatment of atrial fibrillation remaining after completion of pulmonary vein isolation (list separately in addition to code for primary procedure)	7.50	7.50	Finalize
93925	Duplex scan of lower extremity arteries or arterial bypass grafts; complete bilateral study	0.80	0.80	Finalize

HCPCS Code	Long Descriptor	CY 2013 Work RVU	CY 2014 Work RVU	CY 2014 Action
93926	Duplex scan of lower extremity arteries or arterial bypass grafts; unilateral or limited study	0.50	0.50	Finalize
93970	Duplex scan of extremity veins including responses to compression and other maneuvers; complete bilateral study	0.70	0.70	Finalize
93971	Duplex scan of extremity veins including responses to compression and other maneuvers; unilateral or limited study	0.45	0.45	Finalize
95017	Allergy testing, any combination of percutaneous (scratch, puncture, prick) and intracutaneous (intradermal), sequential and incremental, with venoms, immediate type reaction, including test interpretation and report, specify number of tests	0.07	0.07	Finalize
95018	Allergy testing, any combination of percutaneous (scratch, puncture, prick) and intracutaneous (intradermal), sequential and incremental, with drugs or biologicals, immediate type reaction, including test interpretation and report, specify number of tests	0.14	0.14	Finalize
95076	Ingestion challenge test (sequential and incremental ingestion of test items, eg, food, drug or other substance); initial 120 minutes of testing	1.50	1.50	Finalize
95079	Ingestion challenge test (sequential and incremental ingestion of test items, eg, food, drug or other substance); each additional 60 minutes of testing (list separately in addition to code for primary procedure)	1.38	1.38	Finalize
95782	Polysomnography; younger than 6 years, sleep staging with 4 or more additional parameters of sleep, attended by a technologist	2.60	2.60	Finalize
95783	Polysomnography; younger than 6 years, sleep staging with 4 or more additional parameters of sleep, with initiation of continuous positive airway pressure therapy or bi-level ventilation, attended by a technologist	2.83	2.83	Finalize
95860	Needle electromyography; 1 extremity with or without related paraspinal areas	0.96	0.96	Finalize
95861	Needle electromyography; 2 extremities with or without related paraspinal areas	1.54	1.54	Finalize
95863	Needle electromyography; 3 extremities with or without related paraspinal areas	1.87	1.87	Finalize

HCPCS Code	Long Descriptor	CY 2013 Work RVU	CY 2014 Work RVU	CY 2014 Action
95864	Needle electromyography; 4 extremities with or without related paraspinal areas	1.99	1.99	Finalize
95865	Needle electromyography; larynx	1.57	1.57	Finalize
95866	Needle electromyography; hemidiaphragm	1.25	1.25	Finalize
95867	Needle electromyography; cranial nerve supplied muscle(s), unilateral	0.79	0.79	Finalize
95868	Needle electromyography; cranial nerve supplied muscles, bilateral	1.18	1.18	Finalize
95869	Needle electromyography; thoracic paraspinal muscles (excluding t1 or t12)	0.37	0.37	Finalize
95870	Needle electromyography; limited study of muscles in 1 extremity or non-limb (axial) muscles (unilateral or bilateral), other than thoracic paraspinal, cranial nerve supplied muscles, or sphincters	0.37	0.37	Finalize
95885	Needle electromyography, each extremity, with related paraspinal areas, when performed, done with nerve conduction, amplitude and latency/velocity study; limited (list separately in addition to code for primary procedure)	0.35	0.35	Finalize
95886	Needle electromyography, each extremity, with related paraspinal areas, when performed, done with nerve conduction, amplitude and latency/velocity study; complete, five or more muscles studied, innervated by three or more nerves or four or more spinal levels (list separately in addition to code for primary procedure)	0.70	0.86	Finalize
95887	Needle electromyography, non-extremity (cranial nerve supplied or axial) muscle(s) done with nerve conduction, amplitude and latency/velocity study (list separately in addition to code for primary procedure)	0.47	0.71	Finalize
95905	Motor and/or sensory nerve conduction, using preconfigured electrode array(s), amplitude and latency/velocity study, each limb, includes f-wave study when performed, with interpretation and report;	0.05	0.05	Finalize
95907	Nerve conduction studies; 1-2 studies	1.00	1.00	Finalize
95908	Nerve conduction studies; 3-4 studies	1.25	1.25	Finalize
95909	Nerve conduction studies; 5-6 studies	1.50	1.50	Finalize
95910	Nerve conduction studies; 7-8 studies	2.00	2.00	Finalize

HCPCS	Long Descriptor	CY 2013 Work	CY 2014 Work	CY 2014
Code		RVU	RVU	Action
95911	Nerve conduction studies; 9-10 studies	2.50	2.50	Finalize
95912	Nerve conduction studies; 11-12 studies	3.00	3.00	Finalize
95913	Nerve conduction studies; 13 or more studies	3.56	3.56	Finalize
95921	Testing of autonomic nervous system function; cardiovagal innervation (parasympathetic function), including 2 or more of the following: heart rate response to deep breathing with recorded r-r interval, valsalva ratio, and 30:15 ratio	0.90	0.90	Finalize
95922	Testing of autonomic nervous system function; vasomotor adrenergic innervation (sympathetic adrenergic function), including beat-to-beat blood pressure and r-r interval changes during valsalva maneuver and at least 5 minutes of passive tilt	0.96	0.96	Finalize
95923	Testing of autonomic nervous system function; sudomotor, including 1 or more of the following: quantitative sudomotor axon reflex test (qsart), silastic sweat imprint, thermoregulatory sweat test, and changes in sympathetic skin potential	0.90	0.90	Finalize
95924	Testing of autonomic nervous system function; combined parasympathetic and sympathetic adrenergic function testing with at least 5 minutes of passive tilt	1.73	1.73	Finalize
95925	Short-latency somatosensory evoked potential study, stimulation of any/all peripheral nerves or skin sites, recording from the central nervous system; in upper limbs	0.54	0.54	Finalize
95926	Short-latency somatosensory evoked potential study, stimulation of any/all peripheral nerves or skin sites, recording from the central nervous system; in lower limbs	0.54	0.54	Finalize
95928	Central motor evoked potential study (transcranial motor stimulation); upper limbs	1.50	1.50	Interim Final
95929	Central motor evoked potential study (transcranial motor stimulation); lower limbs	1.50	1.50	Interim Final
95938	Short-latency somatosensory evoked potential study, stimulation of any/all peripheral nerves or skin sites, recording from the central nervous system; in upper and lower limbs	0.86	0.86	Finalize
95939	Central motor evoked potential study (transcranial motor stimulation); in upper and lower limbs	2.25	2.25	Finalize

HCPCS Code	Long Descriptor	CY 2013 Work RVU	CY 2014 Work RVU	CY 2014 Action
95940	Continuous intraoperative neurophysiology monitoring in the operating room, one on one monitoring requiring personal attendance, each 15 minutes (list separately in addition to code for primary procedure)	0.60	0.60	Finalize
95941	Continuous intraoperative neurophysiology monitoring, from outside the operating room (remote or nearby) or for monitoring of more than one case while in the operating room, per hour (list separately in addition to code for primary procedure)	I	I	Finalize
95943	Simultaneous, independent, quantitative measures of both parasympathetic function and sympathetic function, based on time-frequency analysis of heart rate variability concurrent with time-frequency analysis of continuous respiratory activity, with mean heart rate and blood pressure measures, during rest, paced (deep) breathing, valsalva maneuvers, and head-up postural change	С	С	Finalize
96920	Laser treatment for inflammatory skin disease (psoriasis); total area less than 250 sq cm	1.15	1.15	Finalize
96921	Laser treatment for inflammatory skin disease (psoriasis); 250 sq cm to 500 sq cm	1.30	1.30	Finalize
96922	Laser treatment for inflammatory skin disease (psoriasis); over 500 sq cm	2.10	2.10	Finalize
97150	Therapeutic procedure(s), group (2 or more individuals)	0.65	0.29	Finalize
99485	Supervision by a control physician of interfacility transport care of the critically ill or critically injured pediatric patient, 24 months of age or younger, includes two-way communication with transport team before transport, at the referring facility and during the transport, including data interpretation and report; first 30 minutes	В	В	Finalize
99486	Supervision by a control physician of interfacility transport care of the critically ill or critically injured pediatric patient, 24 months of age or younger, includes two-way communication with transport team before transport, at the referring facility and during the transport, including data interpretation and report; each additional 30 minutes (list separately in addition to code for primary procedure)	В	В	Finalize

HCPCS Code	Long Descriptor	CY 2013 Work RVU	CY 2014 Work RVU	CY 2014 Action
99487	Complex chronic care coordination services; first hour of clinical staff time directed by a physician or other qualified health care professional with no face-to-face visit, per calendar month	В	В	Finalize
99488	Complex chronic care coordination services; first hour of clinical staff time directed by a physician or other qualified health care professional with one face-to-face visit, per calendar month	В	В	Finalize
99489	Complex chronic care coordination services; each additional 30 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month (list separately in addition to code for primary procedure)	В	В	Finalize
99495	Transitional care management services with the following required elements: communication (direct contact, telephone, electronic) with the patient and/or caregiver within 2 business days of discharge medical decision making of at least moderate complexity during the service period face-to-face visit, within 14 calendar days of discharge	2.11	2.11	Finalize
99496	Transitional care management services with the following required elements: communication (direct contact, telephone, electronic) with the patient and/or caregiver within 2 business days of discharge medical decision making of high complexity during the service period face-to-face visit, within 7 calendar days of discharge (do not report 90951-90970, 98960-98962, 98966-98969, 99071, 99078, 99080, 99090, 99091, 99339, 99340, 99358, 99359, 99363, 99364, 99366-99368, 99374-99380, 99441-99444, 99487-99489, 99605-99607 when performed during the service time of codes 99495 or 99496)	3.05	3.05	Finalize
G0127	Trimming of dystrophic nails, any number	0.17	0.17	Finalize
G0416	Surgical pathology, gross and microscopic examinations for prostate needle biopsy, any method, 10-20 specimens	3.09	3.09	Finalize
G0452	Molecular pathology procedure; physician interpretation and report	0.37	0.37	Finalize

HCPCS Code	Long Descriptor	CY 2013 Work RVU	CY 2014 Work RVU	CY 2014 Action
G0453	Continuous intraoperative neurophysiology monitoring, from outside the operating room (remote or nearby), per patient, (attention directed exclusively to one patient) each 15 minutes (list in addition to primary procedure)	0.5	0.6	Finalize
G0455	Preparation with instillation of fecal microbiota by any method, including assessment of donor specimen	0.97	1.34	Finalize
G0456	Negative pressure wound therapy, (e.g. vacuum assisted drainage collection) using a mechanically-powered device, not durable medical equipment, including provision of cartridge and dressing(s), topical application(s), wound assessment, and instructions for ongoing care, per session; total wounds(s) surface area less than or equal to 50 square centimeters	С	С	Finalize
G0457	Negative pressure wound therapy, (e.g. vacuum assisted drainage collection) using a mechanically-powered device, not durable medical equipment, including provision of cartridge and dressing(s), topical application(s), wound assessment, and instructions for ongoing care, per session; total wounds(s) surface area greater than 50 square centimeters	С	С	Finalize

In the following section, we discuss all codes for which we received a comment on the CY 2013 interim final work value or time during the comment period for the CY 2013 final rule with comment period or codes for which we are modifying the work RVU or time. If a code in Table 24 is not discussed in this section, we did not receive any comments on that code and are finalizing the CY 2013 interim final value.

(1) Integumentary System: Skin, Subcutaneous, and Accessory Structures (CPT code 10120)

As detailed in the CY 2013 final rule with comment period, CPT code 10120 had previously been identified as potentially misvalued using the Harvard-valued utilization over 30,000 screen. We assigned an interim final work RVU of 1.22 for CY 2013, which was slightly less than the AMA RUC-

recommended value of 1.25. The AMA RUC recommendation was based upon survey results; however, we believed an RVU of 1.25 overstated the work of this procedure because some of the activities furnished during the postservice period of the procedure code overlapped with the E/M visit. The AMA RUC appropriately accounted for the overlap with the E/M visit in its recommendation of preservice time, but we believed the recommendation failed to account for the overlap in the postservice time. To account for this overlap, we used our standard methodology as described above. As noted in the CY 2013 final rule with comment period, we refined the time to equal 3 minutes in the postservice physician time for CPT code 10120 for CY 2013.

Comment: Commenters urged us to use the AMA RUC-recommended work value of 1.25 RVUs and postservice physician time of 5 minutes for CPT code 10120. Commenters stated that the AMA RUC conducted extensive review of Medicare claims data for services billed together and after discussing the potential overlap and explicitly determined physician time recommendations that did not include overlap with an E/M service. Since in their view, there was no overlap between the physician time and the E/M service, they recommended that we value the code as recommended by the AMA RUC.

Response: After re-review, we maintain that some of the activities conducted during the postservice time of the procedure code and the E/M visit overlap and, therefore, should not be counted twice in developing the procedure's work value. We continue to believe that the recommended postservice time should be reduced by one-third to account for this overlap. To calculate the time, we reduced the survey's median postservice time of 5 minutes by one-third, resulting in a reduction from 5 minutes to 3 minutes. As such, we also continue to believe that a work RVU of 1.22 accurately reflects the work of the service relative to similar services. Therefore, we are finalizing a work RVU of 1.22 for CPT code 10120 and the time refinement as established for CY 2014.

(2) Integumentary System: Skin, Subcutaneous, and Accessory Structures (CPT codes 11302, 11306, 11310, 11311, 11312, and 11313)

For these codes, as we discussed in the CY 2013 final rule with comment period, we set the work RVUs at the survey's 25th percentile work RVUs as we believed this reflected the appropriate relativity of

the services both within this family as well as relative to other PFS services. As noted in the CY 2013 final rule with comment period, our interim final values differed from the AMA RUC recommendation for CPT codes 11302, 11306, 11310, 11311, 11312 and 11313.

<u>Comment:</u> Commenters expressed disappointment with our CY 2013 interim final values for CPT codes 11302, 11306, 11310, 11311, 11312, and 11313, but without providing reasons to support a higher value.

Response: We continue to believe that the survey's 25th percentile RVUs accurately reflect the work of these procedures relative to each other and relative to other procedures. Therefore, for CY 2014 we are finalizing the CY 2013 interim final work RVU values for CPT codes 11302, 11306, 11310, 11311, 11312 and 11313.

(3) Integumentary System: Repair (Closure) (CPT codes 13132, 13150, 11351, and 13152)

For CY 2013, we received new recommendations from the AMA RUC for the complex wound repair family, including CPT codes 13132, 13150, 13151, and 13152. As we described in the CY 2013 final rule with comment period, we assigned CY 2013 interim final work RVUs consistent with AMA RUC recommendations for all the codes in this complex wound repair family, except CPT codes 13150 and 13152, as discussed below. We assigned the following CY 2013 interim final work RVUs: 4.78 for CPT code 13132, 3.58 for CPT code 13150, 4.34 for CPT code 13151 and 2.38 for CPT code 13153.

<u>Comment</u>: Commenters agreed with our interim final work RVUs of 4.78 for CPT code 13132 and 4.34 for CPT code 13151 and thanked us for accepting the AMA RUC-recommendations.

Response: We are finalizing work RVUs for CY 2014 of 4.78 for CPT code 13132 and 4.34 for CPT code 13151.

The AMA RUC did not provide a recommendation for CPT code 13150 for CY 2013 with

the other codes in the family because it was expecting that code to be deleted for CY 2014. As we noted in the CY 2013 final rule with comment period, we believed it was appropriate to reduce the work RVU of CPT code 13150 proportionate to the reductions in work RVUs that the AMA RUC recommended and we adopted for other services in the family, so that we maintained appropriate proportionate rank order for CY 2013. For the 12 other CPT codes in the family, their CY 2012 work RVUs were reduced, on average, by 7 percent for CY 2013. Applying that reduction to the work RVU of CPT code 13150 resulted in a CY 2013 work RVU of 3.58. We believed that value appropriately reflected the work associated with the procedure and we assigned a CY 2013 interim final work RVU of 3.58 to CPT code 13150. This code will be deleted effective January 1, 2014.

As we noted in the CY 2013 final rule with comment period, after reviewing CPT code 13152, we believed that the AMA RUC-recommended work RVU of 5.34 was too high relative to similar CPT code 13132, which had an AMA RUC-recommended work RVU of 4.78, and CPT code 13151, which had an AMA RUC-recommended work RVU of 4.34. We believed that the survey's 25th percentile work RVU of 4.90 more appropriately reflected the relative work involved in furnishing the service. Therefore, we assigned a CY 2013 interim final work RVU of 4.90 for CPT code 13152.

Comment: Commenters disagreed with our relative comparison of CPT code 13152 to CPT codes 13132 and 13151. Commenters stated that the AMA RUC determined that the survey's 25th percentile work RVU of 4.90 was too low for CPT code 13152 and would cause a rank order anomaly when compared to the less intense CPT code 13132. One commenter cited the detailed rationale that they presented to the AMA RUC explaining how CPT code 13152 was more intense and complex to perform than CPT code 13132. Furthermore, commenters

supported the AMA RUC-recommended direct crosswalk of CPT code 13152 to CPT code 36571, which has a work RVU of 5.34. Commenters requested that we use the AMA RUC-recommended work RVU of 5.34 for CPT code 13152.

Response: Based on comments received, we re-reviewed CPT code 13152 and agree based on the complexity and intensity of the service that CPT code 13152 is more appropriately directly crosswalked to CPT code 36571 which has a work RVU of 5.34. Therefore, we are finalizing the AMA RUC-recommended work RVU of 5.34 to CPT code 13152 for CY 2014.

(4) Arthrocentesis (CPT Code 20605)

In the CY 2013 final rule with comment period, we revised the direct PE inputs for CPT code 20605 (Arthrocentesis, aspiration and/or injection; intermediate joint or bursa (eg, temporomandibular, acromioclavicular, wrist, elbow or ankle, olecranon bursa)) and valued the code on an interim final basis for CY 2013. We had revised the work RVU for this code in CY 2012. In CY 2012, when we revised the work RVU, we established a value of 0.68 (76 FR 73209). However, in CY 2013 due to a data entry error, a work RVU of 0.98 was used for CPT 20605. Subsequent to the publication of the proposed rule, a stakeholder alerted us to a work RVU discrepancy for this code. The values displayed in Addenda B and C of the CY 2013 final rule with comment period reflect this error. In this final rule with comment period we are making a technical correction to the work RVU, revising it to 0.68, which is the work value we established in CY 2012.

(5) Musculoskeletal System: Spine (Vertebral Column) (CPT code 22586)

CPT code 22586 was created by the CPT Editorial Panel effective January 1, CY 2013. As we noted in the CY 2013 final rule with comment period, after clinical review of CPT code 22586, we believed that a work RVU of 28.12 accurately accounted for the work associated with the service and assigned this as the CY 2013 interim final value. The AMA RUC did not provide a recommendation on this service because the specialty societies that would have needed to conduct a survey as part of the AMA RUC process declined to do so. We also noted that a specialty society that does not participate in

the AMA RUC conducted a survey of its members, who furnish this service, regarding the work and time associated with this procedure and submitted a work RVU recommendation to CMS.

In the CY 2013 final rule with comment period we noted that in determining the appropriate value for this new CPT code, we reviewed the survey results and recommendations submitted to us, literature on the procedure, and Medicare claims data. Ultimately, we used a building block approach to value CPT code 22586. As we stated in the CY 2013 final rule with comment period, we valued CPT 22586 using CPT code 22558 as a reference service. CPT code 22558 is a similar procedure except that it does not include additional grafting, instrumentation, and fixation that are included in CPT code 22586. To assess the appropriate relative work increase from unbundled CPT code 22558 to the new bundled CPT code 22586, we used Medicare claims data to assess which grafting, instrumentation, and fixation services were commonly billed with CPT code 22558. Using these data we created a utilization-weighted work RVU for the grafting component of CPT code 22586, the instrumentation component of the 22586, and the fixation component of 22586. Adding these work RVUs to those of CPT code 22558 created a work RVU of 28.12, which we assigned as the CY 2013 interim final work RVU for CPT code 22586.

Additionally, as detailed in the CY 2013 final rule with comment period, after reviewing the physician time and post-operative visits for similar services, we concluded that this service includes 40 minutes of preservice evaluation time, 20 minutes of preservice positioning time, 20 minutes of preservice scrub, dress and wait time, 180 minutes of intraservice time, and 30 minutes of immediate postservice time. In the post-operative period, we believed that this service typically includes 2 CPT code 99231 visits, 1 CPT code 99323 visit, 1 CPT code 99238 visit, and 4 CPT code 99213 visits.

Comment: A commenter opposed our use of the building block methodology to value CPT code 22586, noting that we had used a methodology that digressed from our current standards for valuing procedures. Additionally, the commenter disagreed with our use of data from a specialty society that does not participate in the AMA RUC.

<u>Response</u>: To properly value this service without an AMA RUC recommendation, we believe that our evaluation of survey results, recommendations, literature, and Medicare claims data is crucial.

Additionally, as we stated in the methodology section above and in previous final rules with comment periods, we believe the building block methodology is an appropriate approach to develop RVUs. We continue to believe the methodology used to develop the CY 2013 interim final work RVU using CPT code 22588 as the base reference is suitable for this code. Furthermore, we believe that the interim final work RVU accurately reflects the work of the typical case and reflects the appropriate incremental difference in work between CPT code 22588 and new CPT code 22586. Therefore, we are finalizing a work RVU of 28.12 for CPT code 22586 for CY 2014.

(6) Elbow Implant Removal (CPT code 24160)

As detailed in the CY 2013 final rule with comment period, we maintained the current work value for CPT code 24160 based upon the AMA RUC recommendation. We received an AMA RUC recommendation for a work RVU of 18.63 based upon a revised CPT code description for this code. We agree with the AMA RUC recommendation and are assigning a CY 2014 interim final work RVU of 18.63 to CPT code 24160.

As detailed in the CY 2013 final rule with comment period, in response to comments we received in response to the CY 2012 final rule with comment period, we referred CPT code 29581 to the CY 2012 multi-specialty refinement panel for further review. The refinement panel median work RVU for CPT code 29581 was 0.50. Typically, we finalize the work values for CPT codes after reviewing the results of the refinement panel. However, for CY 2012 we assigned interim RVUs for CPT codes 29581, 29582, 29583, and 29584 and requested additional information, with the intention of re-reviewing the services for CY 2013 with the new information we had received, and setting interim final values at that time. After consideration of the public comments, refinement panel median value, and our clinical review, we continued to believe that a work RVU of 0.25 was appropriate for CPT code 29581. We recognized that CPT code 29581 received only editorial changes in CY 2012; however, we continued to believe the HCPAC-reviewed codes 29582, 29583, and 29584 describe similar services. While the services are performed by different specialties, they do involve similar work. Therefore, we continued to believe that crosswalking CPT code 29581 to CPT codes 29582, 29583 and 29584 was appropriate and that the

resulting work RVU accurately reflected the work associated with the service. Accordingly, on an interim final basis for CY 2013, we assigned a work RVU of 0.25 to CPT code 29581; a work RVU of 0.35 to CPT code 29582; a work RVU of 0.25 to CPT code 29583; and a work RVU of 0.35 to CPT code 29584.

Comment: Commenters disagreed with our crosswalk of CPT 29581 to CPT codes 29582, 29583, and 29584. Commenters stated that it was incorrect to compare CPT code 29581 to the other codes in the family because the typical patient for CPT 29581, a patient with a recalcitrant venous ulcer, is entirely different and more complex than the typical patient for the other codes, and as a result, CPT 29581 is a more intense and time-consuming service. Therefore, commenters requested that we use the AMA RUC-recommended work RVU of 0.60 for CPT code 29581.

Response: After re-review of CPT code 29581, we maintain that a crosswalk to CPT codes 29582, 29583, and 29584 is appropriate because the services involve similar work and as such, should be valued relative to one another. Even though the typical patient for CPT code 29581 may be different than CPT codes 29582, 29583, and 29584, the work associated with the service is not necessarily different. Accordingly, we continue to believe that our recommended value accurately reflects the work of the procedure and are finalizing a work RVU of 0.25 for CPT code 29581 for CY 2014.

(8) Respiratory System: Accessory Sinuses (CPT code 31231)

Previously, CPT code 31231 was identified for review because it was on the multispecialty points of comparison list. We assigned a CY 2013 interim final work RVU of 1.10 to CPT code 31231, which was the survey's 25th percentile value and the AMA RUC recommendation. We believed that some of the activities furnished during the preservice and postservice period of the procedure code and the E/M visit overlapped and, therefore, should not be counted twice in developing the procedure's work value.

Although we believed the AMA RUC appropriately accounted for this overlap in its recommendation of preservice time, we believed they did not account for the overlap in the postservice time. To account for this overlap, we reduced the postservice time by one-third. Specifically, we reduced the postservice time from 5 minutes to 3 minutes.

Comment: Although commenters supported the use of the AMA RUC-recommended work RVU, they overwhelmingly disagreed with lowering the postservice time for CPT code 31231. Commenters stated that the AMA RUC valued CPT code 31231 through significant review of Medicare claims data for services billed together and deliberations on potential overlap, and determined physician time recommendations that did not include overlap with an E/M service. The commenters stated that none of the post-time allocated to this code overlapped with the E/M service. Therefore, commenters requested our acceptance of the AMA RUC-recommended postservice physician time of 5 minutes.

Response: After re-review, we maintain that some of the activities conducted during the postservice time of the procedure code and the E/M visit overlap and, therefore, should not be counted twice in developing the procedure's work value. To account for this overlap, we used our standard methodology as described above. Therefore, we are finalizing a refinement of postservice time and a work RVU of 1.10 for CPT code 31231 for CY 2014.

(9) Respiratory System: Trachea and Bronchi (CPT codes 31647, 31648, 31649 and 31651)

Effective January 1, 2013, the CPT Editorial Panel created CPT codes 31647, 31648, 31649, and 31651 to replace 0250T, 0251T; and CPT codes 31660 and 31661 to replace 0276T and 0277T. As we noted in the CY 2013 final rule with comment period when we valued these codes for the first time, we assigned a work RVU of 4.40 to CPT code 31647; a work RVU of 4.20 to CPT code 31648; and a work RVU of 1.58 to CPT code 31651 on an interim final basis for CY 2013, based upon the AMA RUC recommendations for these codes.

<u>Comment</u>: Commenters agreed with our interim final work for these codes and thanked us for accepting the AMA RUC recommendations.

Response: We are finalizing work RVUs of 4.40 for CPT code 31647, 4.20 for CPT code 31648 and 1.58 for CPT code 31651 for CY 2014.

As we noted in the CY 2013 final rule with comment period, after clinical review, we did not agree with the AMA RUC-recommended work RVU of 2.00 for CPT code 31649. Since CPT code 31647 had a higher work RVU than CPT code 31648, we believed that to maintain the appropriate relativity between the services, the add-on code associated with CPT code 31647 (CPT code 31651) should have a higher RVU than the add-on code associated with CPT code 31648 (CPT code 31649). We believed that by valuing CPT code 31649 at the survey's 25th percentile work RVU of 1.44, the services were placed in the appropriate rank order. Therefore, we assigned a CY 2013 interim final work RVU of 1.44 to CPT code 31649.

<u>Comment</u>: Commenters urged us to use the AMA RUC-recommended work value of 2.00 for CPT code 31649 and requested that we refer the code to the refinement panel. They noted that proper relativity would have CPT code 31649 ranked higher than CPT code 31651 due to the fact that valve removal requires greater physician intensity and complexity compared to insertion.

Response: After evaluation of the request for refinement, we determined that the criteria for the request for refinement were not met and, as a result, we did not refer CPT code 31649 to the CY 2013 multi-specialty refinement panel for further review.

After re-review of the work RVUs for CPT code 31649 in light of the comments submitted, we maintain that our approach in valuing this procedure is appropriate. Additionally, during clinical rereview we examined in great detail the physician intensity and complexity involved in CPT code 31649 and believe that the survey's 25th percentile work RVU of 1.44 adequately captures these factors. Furthermore, we believe that the CY 2013 interim final work RVU accurately reflects the work of the typical case and reflects the appropriate incremental difference in work with CPT code 31651. Therefore, we are finalizing a work RVU of 1.44 for CPT code 31649 for CY 2014.

(10) Respiratory System: Lungs and Pleura (CPT codes 32551 and 32557)

We assigned CPT code 32551 a CY 2013 interim final work RVU of 3.29. As we noted in the CY 2013 final rule with comment period, we did not believe that the 0.21 work RVU

increase recommended by the AMA RUC based upon the survey's 25th percentile work RVU of 3.50 was warranted for this service, especially considering the substantial reduction in recommended physician time. Additionally, as we noted in the CY 2013 interim final rule with comment period, we believed that a work RVU of 3.29 placed this service in the appropriate rank order with the other similar CPT codes reviewed for CY 2013.

Comment: A commenter stated CPT code 32551 should have been assigned a higher work value than we assigned in CY 2013 and requested that we use the AMA RUC-recommended work value for the service. The commenter also pointed out that the work RVU value for 32551 was reduced a few years ago to account for the vast number of percutaneous catheter insertions billed with this code. Because the percutaneous placed catheters, which involve less work, have since been given their own code set, the commenter stated that the open chest tube insertion would be the only procedure for which CPT code 32551 could be used. As such, the commenter believed that if we accepted the idea that a "properly valued code can be split into less complex and intense (percutaneous catheter insertion) with lesser value and more complex and intense (32551, open thoracostomy) of greater value, [we] would have an appropriate rationale for accepting the RUC recommendations (25th percentile of the survey, 3.50 RVW) for 32551."

Response: After review of the comments, we continue to believe that an increase in work RVU for CPT code 32551 is inappropriate, especially considering the substantial reduction in the AMA RUC-recommended physician time. Moreover, we believe that the work RVU of 3.29 accurately reflects the work of the typical case of this service. Therefore, we are finalizing a work RVU of 3.29 for CPT code 32551 for CY 2014.

As detailed in the CY 2013 final rule with comment period, CPT code 32557 was created as part of a coding restructure for this family. This code was assigned a CY 2013 interim final

work RVU of 3.12 because we believed the AMA RUC-recommended work RVU of 3.62 overstated the difference between this code and CPT code 32556, which had an AMA RUC-recommended work RVU of 2.50. The specialty societies that surveyed CPT code 32556 recommended to the AMA RUC a work RVU of 3.00 for CPT code 32556 and a work RVU of 3.62 for CPT code 32557. We believed this difference of 0.62 in work RVUs between the two codes more accurately captured the relative difference between the services. Therefore, since we assigned CPT code 32556 a CY 2013 interim final work RVU of 2.50, we believed a work RVU of 3.12 reflected the appropriate difference between CPT codes 32556 and 32557 and appropriately reflected the work of CPT code 32557.

Additionally, in CY 2013, we refined the AMA RUC-recommended preservice evaluation time from 15 minutes to 13 minutes for CPT code 32557 to match the preservice evaluation time of CPT code 32556.

Comment: Commenters stated that we did not comprehend the relationship between the base code, CPT code 32556, without imaging, and CPT code 32557, with imaging, and the significant clinical differences in providing the services. Commenters disagreed with the way we determined the work RVU for CPT 32557 and stated that a better alternative for valuing CPT code 32557 would have been to add the value of CT guidance (1.19) to the non-image guided code (CPT code 32556 at 2.50 RVUs) to achieve the AMA RUC-recommended work RVU of 3.62. Therefore, commenters requested our use of the AMA RUC-recommended work value of 3.62 for CPT code 32557 and refinement panel review of the code.

Response: After evaluation of the request for refinement, we determined that the criteria for the request for refinement were not met and, as a result, we did not refer CPT code 32557 to the CY 2013 multi-specialty refinement panel for further review.

After re-review of CPT code 32557, we maintain that our approach in valuing this procedure is appropriate since the AMA RUC-recommended work RVU of 3.62 overstates the difference between CPT codes 32556 and 32557. We continue to believe that the difference in work RVUs presented to the AMA RUC by the specialty societies that surveyed CPT code 32557 is more appropriate in order to maintain relativity among the codes. Therefore, we are finalizing the refinement to time and the work RVU of 3.12 for CPT code 32557 for CY 2014. (11) Respiratory System: Lungs and Pleura (CPT codes 32663, 32668, 32669, 32670, 32671, 32672, and 32673)

The CPT Editorial Panel reviewed the lung resection family of codes and deleted 8 codes, revised 5 codes, and created 18 new codes for CY 2012. As detailed in the CY 2012 final rule with comment period, during our review for the CY 2012 PFS final rule with comment period, we were concerned with the varying differentials in the AMA RUC-recommended work RVUs and times between some of the open surgery lung resection codes and their endoscopic analogs. Rather than assign alternate interim final RVUs and times in this large restructured family of codes, we accepted the AMA RUC recommendations on an interim basis for CY 2012 and requested that the AMA RUC re-review the surgical services along with their endoscopic analogs.

In the CY 2012 PFS final rule with comment period we made this request. However, there was an inadvertent typographical error in our request, in that we referred to "open heart surgery analogs" instead of just "open surgery analogs" for each code. For example, we stated, "For CPT code 32663 (Thoracoscopy, surgical; with lobectomy (single lobe)), the AMA RUC recommended a work RVU of 24.64. Upon clinical review, we have determined that it is most appropriate to accept the AMA RUC-recommended work RVU of 24.64 on a provisional basis, pending review of the open heart surgery analogs, in this case CPT code 32480. We are requesting the AMA RUC look at the incremental difference in RVUs and times between the open and laparoscopic surgeries and recommend a consistent valuation of RVUs and time for CPT code 32663 and other services within this family with this same

issue. Accordingly, we are assigning a work RVU of 24.64 for CPT code 32663 on an interim basis for CY 2012" (76 FR 73195). During the comment period on the CY 2012 final rule with comment period, the affected specialty societies and the AMA RUC responded to our request noting that the codes were not open heart surgery codes.

In the CY 2013 final rule with comment period, we acknowledged that our request would have been more clear if we had referred to "open surgery codes" instead of "open heart surgery codes" and if we had written "endoscopic procedures" instead of "laparoscopic surgeries." With this clarification, we re-requested public comment on the appropriate work RVUs and time values for CPT codes 32663 and 32668-32673. For CY 2013, we maintained the following CY 2012 interim final values for these services as shown in Table 24.

Comment: A commenter stated that there was no apparent correlation between the endoscopic and open variations of the procedures and added that no further effort was needed to determine differences between the two approaches because "any such relationship would be spurious at best." The commenter also stated that additional "exercises to establish consistent differences in work value according to surgical approach (when such relationships actually do not exist for clinical reasons)" are unnecessary.

Response: We continue to believe that our request for additional information on the relationship between open and endoscopic procedures was warranted. Because we received no additional information on this family, as requested, we are finalizing our CY 2013 interim final values for this family.

(12) Cardiovascular System: Heart and Pericardium (CPT codes 33361, 33362, 33363, 33364, 33365, 33367, 33368, 33405, 33430, and 33533)

As detailed in the CY 2013 final rule with comment period, the CPT Editorial Panel deleted four Category III codes (0256T through 0259T) and created nine CPT codes (33361 through 33369) to report transcatheter aortic valve replacement (TAVR) procedures for CY 2012.

Like their predecessor Category III codes (0256T-0259T), the new Category I CPT codes 33361 through 33365 require the work of an interventional cardiologist and cardiothoracic surgeon to jointly participate in the intra-operative technical aspects of TAVR as co-surgeons. Claims processing instructions for the Coverage with Evidence Development (CED) (CR 7897 transmittal 2552) requires each physician to bill with modifier -62 indicating that the co-surgery payment applies. In this situation, Medicare pays each co-surgeon 62.5 percent of the fee schedule amount. The three add-on cardiopulmonary bypass support services (CPT codes 33367, 33368, and 33369) are only reported by the cardiothoracic surgeon; therefore the AMA RUC-recommended work RVUs for those services reflected only the work of one physician. The AMA RUC-recommended work RVUs for each of the co-surgery CPT codes (33361 through 33365) reflect the combined work of both physicians without any adjustment to reflect the co-surgery payment policy. As we noted in the CY 2013 final rule with comment period, we considered whether it was appropriate to continue our co-surgery payment policy at 62.5 percent of the physician fee schedule amount for each physician for these codes if the work value reflected 100 percent of the work for two physicians. Ultimately, we decided to set the work RVU values to reflect the total work of the procedures, and to continue to follow our co-surgery payment policy, which allows the services to be billed by two physicians in part because this was part of the payment policy established with the CED decision.

As we noted in the CY 2013 final rule with comment period, after clinical review of CPT code 33361, we believed that the survey's 25th percentile work RVU of 25.13 appropriately captured the total work of the service. The AMA RUC recommended the survey's median work RVU of 29.50. Regarding physician time, for CPT 33361, as well as CPT codes 33362 through 33364, we believed 45 minutes of preservice evaluation time, which was the survey median time, was more consistent with the work of this service than the AMA RUC-recommended preservice evaluation time of 50 minutes. Accordingly, we assigned a work RVU of 25.13 to CPT code

33361, with a refinement of 45 minutes of preservice evaluation time, on an interim final basis for CY 2013.

As we explained in the CY 2013 interim final rule with comment period, after clinical review of CPT code 33362, we believed that the survey's 25th percentile work RVU of 27.52 appropriately captured the total work of the service and assigned an interim final work RVU of 27.52. The AMA RUC recommended the survey median work RVU of 32.00. As with CPT code 33361, we believed 45 minutes of preservice evaluation time was more appropriate for this service than the AMA RUC recommended preservice evaluation time of 50 minutes. We therefore refined the preservice evaluation time to 45 minutes.

As we noted in the CY 2013 interim final rule with comment period, after clinical review of CPT code 33363, we believed that the survey's 25th percentile work RVU of 28.50 appropriately captured the total work of the service and assigned an interim final work RVU of 28.50. The AMA RUC recommended the survey median work RVU of 33.00. As with CPT codes 33361 and 33362, we believed 45 minutes of preservice evaluation time was more appropriate for this service than the AMA RUC recommended time of 50 minutes and we therefore refined the preservice evaluation time to 45 minutes.

As we noted in the CY 2013 final rule with comment period, after clinical review of CPT code 33364, we believed that the survey's 25th percentile work RVU of 30.00 more appropriately captured the total work of the service than the AMA RUC-recommended survey median work RVU of 34.87, and therefore, we established an interim final work RVU of 30.00. As with CPT codes 33361-33363, we also believed 45 minutes of preservice evaluation time was more appropriate for this service than the AMA RUC-recommended time of 50 minutes, and therefore, we refined the preservice evaluation time 45 minutes.

As we noted in the CY 2013 final rule with comment period, after clinical review of CPT code 33365, we believed a work RVU of 33.12 accurately reflected the work associated with this service rather than the survey's median work RVU of 37.50. We determined that the work associated with this service was similar to reference CPT code 33410, which has a work RVU of 46.41 and has a 90-day global period that includes inpatient hospital and office visits. Because CPT code 33365 had a 0-day global period that does not include post-operative visits, we calculated the value of the pre-operative and post-operative visits in the global period of CPT code 33410, which totaled 13.29 work RVUs, and subtracted that from the total work RVU of 46.41 for CPT code 33410 to determine the appropriate work RVU for CPT code 33365. With regard to time, we used the 50 minutes of preservice evaluation time because we believed that the procedure described by CPT code 33365 involves more preservice evaluation time than 33410 since it was performed by surgically opening the chest via median sternotomy. Accordingly, we assigned an interim final work RVU of 33.12 for CPT code 33365 for CY 2013.

Comment: Commenters disagreed with our use of the 25th percentile survey values for CPT codes 33361-33365 rather than the AMA RUC-recommended median survey values. Commenters stated that our valuation of CPT code 33365 was arbitrary and resulted in considerably undervalued work RVUs. They also asserted that our interim final work RVUs produced rank order anomalies, were inconsistent with the high level of intensity and complexity necessitated by the procedures, and undervalued the procedures for each physician. Additionally, commenters provided examples comparing the AMA RUC recommendations and the interim final work RVUs for CPT codes 33361-33365 to other codes that were recently valued. In providing the examples, commenters made an effort to demonstrate that, by comparing CPT codes 33361-33365 to active comparable CPT codes and through proration of the physician time, it was apparent that the work RVUs for CPT codes 33361-33365 should be increased. Commenters therefore requested we use the AMA RUC-recommended work values of 29.50 for CPT code 33361, 32.00 for CPT code 33362, 33.00 for CPT code 33363, 34.87 for CPT code 33364 and 37.50 for CPT code 33365 and submit the code series to the refinement panel for review.

Response: After evaluation of the request for refinement, we determined that the criteria for the request for refinement were not met and, as a result, we did not refer CPT codes 33361-33365 to the CY 2013 multi-specialty refinement panel for further review.

After consideration of the comments on CPT codes 33361-33365, we maintain that our approach in valuing these procedures is appropriate. We believe that the AMA RUC-recommended work RVUs overstate the intensity and physician time in this family. We also believe that setting the work RVU values of these services to reflect the total work of the procedures is appropriate. This decision is also consistent with our co-surgery payment policy, which allows the services to be billed by two physicians. While many commenters objected to this rationale, we believe that their comparisons of CPT codes 33361-33365, services that require the work of two physicians, to codes where only one physician is performing the work are inappropriate. We continue to believe that the interim final work RVUs that we established in the CY 2013 final rule with comment period accurately reflect the work of the typical case of this service. Therefore, for CY 2014, we are finalizing the interim final work RVUs for CPT codes 33361-33365. We are also finalizing the following refinements to time for CY 2014: 45 minutes of preservice evaluation for CPT codes 33365.

<u>Comment</u>: Commenters specifically agreed with our interim final work RVUs of 11.88 for CPT code 33367 and 14.39 to CPT code 33368 and thanked us for using the AMA RUC recommendations.

Response: We are finalizing the work RVUs of 11.88 to CPT code 33367 and 14.39 to CPT code 33368 for CY 2014.

As detailed in the CY 2013 final rule with comment period, CPT codes 33405, 33430, and 33533 were previously identified as potentially misvalued through the high expenditure procedure code screen.

When reviewing the services, the specialty society utilized data from the Society of Thoracic Surgeons (STS) National Adult Cardiac Database in developing recommended times and work RVUs for CPT

codes 33405, 33430 and 33533 rather than conducting a survey of work and time. After reviewing the mean procedure times for the services in the STS database alongside other information relating to the value of the services, the AMA RUC concluded that CPT codes 33405 and 33430 were appropriately valued and, accordingly, the CY 2012 RVUs of 41.32 for CPT code 33405, and 50.93 for CPT code 33430 should be maintained, and that the work associated with CPT code 33553 had increased since the service was last reviewed. The AMA RUC recommended a work RVU of 34.98 for CPT code 33533, which is a direct crosswalk to CPT code 33510.

As we noted in the CY 2013 final rule with comment period (77 FR 69049), we believed the STS database, which captures outcome data in addition to time and visit data, is a useful resource in the valuation of services. However, we remain interested in additional data from the STS database that might help provide context to the reported information. The AMA RUC recommendations on the services showed only the STS database mean time for CPT codes 33405, 33430, and 33533. We noted in the CY 2013 final rule with comment period that we were interested in seeing the distribution of times for the 25th percentile, median, and 75th percentile values, in addition to any other information STS believed would be relevant to the valuation of the services. For CY 2013, we assigned interim final work RVUs for the services, pending receipt of additional time data. Specifically, we maintained the CY 2012 work RVU values of 41.32 for CPT code 33405; 50.93 for CPT code 33430; and 33.75 for CPT code 33533.

Comment: STS requested a higher work value of CPT code 33533 and also disagreed with the AMA RUC recommendation. In its opinion, "the RUC recommendation is not consistent with the process and alters the intensity of 33533 contrary to the RUC rationale." In contrast, the AMA RUC stated that the AMA RUC work value recommendation was most appropriate and asked that we submit the code for refinement panel review.

In response to our request for additional information regarding times from the STS database, all commenters declined to provide further information, stating that sufficient time data and explanations for the methodology associated with utilization of the database were provided to both the AMA RUC and CMS. STS further expressed its disinterest in providing additional information by noting that the

supplementary data that we requested, the median or 25th percentile statistical descriptors, would "systematically exclude known physician work from consideration in code valuation, and if utilized would result in undervaluation relative to the remainder of the Physician Fee Schedule."

Response: After evaluation of the request for refinement, we determined that the criteria for the request for refinement were not met and, as a result, we did not refer CPT code 33533 to the CY 2013 multi-specialty refinement panel for further review.

After re-review of CPT codes 33405, 33430 and 33533, we maintain that our approach in valuing these procedures is appropriate. In the CY 2013 final rule with comment period, we expressed our concern with the data derived from the STS database and our desire to receive additional information regarding the distribution of times and varying RVUs, for the 25th percentile, median, and 75th percentile values, in order to better value the services. We did not receive additional information from either STS or the AMA RUC regarding these procedures. In the absence of this information, we continue to believe that the CY 2013 interim final work RVUs for CPT codes 33405, 33430 and 33533 reflect the work of the typical case of these services. Therefore, we are finalizing the work RVUs of 41.32 for CPT code 33405, 50.93 for CPT code 33430 and 33.75 for CPT code 33533 for CY 2014.

(13) Cardiovascular System: Arteries and Veins (CPT codes 35475, 35476, 36221-36227)

In the CY 2013 final rule with comment period, after clinical review of CPT code 35475, we established a work RVU of 5.75 to appropriately capture the work of the service. The AMA RUC, rather than using the survey, used a building block approach based on comparison CPT code 37224, which has a work RVU of 9.00, and recommended a work RVU of 6.60. The AMA RUC acknowledged that CPT code 35475 was typically reported with other services. We determined that the appropriate crosswalk for this code was CPT code 37220, which has a work RVU of 8.15. After accounting for overlap with other services, we determined that a work RVU of 5.75 was appropriate for the service. Accordingly, we assigned a work RVU of 5.75 to CPT code 35475 on an interim final basis for CY 2013.

After clinical review of CPT code 35476, we assigned a work RVU of 4.71 to the service in the CY 2013 final rule with comment period. The AMA RUC had recommended a work RVU of 5.10, based

on the survey's 25th percentile value. We determined that the work associated with CPT code 35476 was similar in terms of physician time and intensity to CPT code 37191, which had a work RVU of 4.71. We believed the work RVU of 4.71 appropriately captured the relative difference between the service and CPT code 35475. Therefore, we assigned a work RVU of 4.71 for CPT code 35476 on an interim final basis for CY 2013.

Comment: Commenters universally disagreed with our reference codes for CPT codes 35475 and 35476. They stated that our comparison of CPT code 35475 to CPT code 37224 did not fully consider intensity or complexity of CPT code 35475, such as the need for a physician to perform catheter manipulation or traverse multiple vessels. They also stated that our comparison of CPT code 35476 to CPT code 37220 was inappropriate because the latter procedure was related to a service in a lower flow vein and, thus, using this crosswalk did not account for the service's work intensity or complexity, including the risk associated with angioplasty. Commenters believed that the comparison codes utilized by the AMA RUC in its recommended valuation, CPT codes 37224 and 37220, had a more comparable level of difficulty to CPT codes 35475 and 35476, respectively, than the codes we used. Additionally, commenters were concerned on a broader policy basis that the interim final values would compromise both the vascular access care provided to chronic kidney disease patients and specialty programs. For those reasons, commenters requested our use of the AMA RUC-recommended work RVUs of 6.60 for CPT code 35475 and 5.10 for CPT code 35476 and refinement panel review of the codes.

Response: We referred CPT codes 35475 and 35476 to the CY 2013 multi-specialty refinement panel for further consideration because the requirements for refinement panel review were met. The refinement panel median work RVU for CPT codes 35475 and 35476 were 6.60 and 5.10, respectively. After reevaluation, we are finalizing work RVUs of 6.60 for CPT code 35475 and 5.10 for CPT code 35476, based upon the refinement panel median.

In the CY 2013 final rule with comment period we assigned CPT code 36221 an interim final work RVU of 4.17 and refined the postservice to 30 minutes. The AMA RUC recommended a work RVU of 4.51 and a postservice time of 40 minutes using a direct crosswalk to the two component codes being

bundled, CPT code 32600, which has a work RVU of 3.02, and CPT code 75650, which has a work RVU of 1.49. As we noted in the CY 2013 final rule with comment period, we believed that that there were efficiencies gained when services were bundled and that crosswalking to the work RVU of CPT code 32550, which had a work RVU of 4.17, appropriately accounted for the physician time and intensity with CPT code 36221. Additionally, we believed that the survey's postservice time of 30 minutes more accurately accounted for the time involved in furnishing the service than the AMA RUC-recommended postservice time of 40 minutes.

In the CY 2013 final rule with comment period we noted that after clinical review of CPT code 36222, we believed the survey 25th percentile work RVU of 5.53 appropriately captured the work of the service, particularly the efficiencies when two services were bundled together. The AMA RUC recommended the survey median work RVU of 6.00. Like CPT code 36221, we believed the survey's postservice time of 30 minutes was more appropriate than the AMA RUC-recommended postservice time of 40 minutes. We assigned a work RVU of 5.53 with refinement to time for CPT code 36222 as interim final for CY 2013.

In the CY 2013 final rule, we noted that after clinical review of CPT code 36223, we assigned an interim final work RVU value of 6.00, the survey's 25th percentile value, because we believed it appropriately captured the work of the service, particularly efficiencies when two services were bundled together. The AMA RUC reviewed the survey results, and after a comparison to similar CPT codes, recommended a work RVU of 6.50. Like many other codes in the family, we believed the survey's postservice time of 30 minutes was more appropriate than the AMA RUC-recommended time of 40 minutes and refined the time accordingly.

In the CY 2013 final rule, we noted that after clinical review of CPT code 36224, we believed a work RVU of 6.50, the survey's 25th percentile value, appropriately captured the work of the service, particularly, efficiencies when two services were bundled together. We believed 30 minutes of postservice time more appropriately accounted for the work of the service. The AMA RUC reviewed the survey results, and after a comparison to similar CPT codes, recommended a value of 7.55 and a postservice time

of 40 minutes for CPT code 36224. Accordingly, we assigned a work RVU of 6.50 with refinement to time for CPT code 36224 as interim final for CY 2013.

In the CY 2013 final rule, we noted that after clinical review of CPT code 36225, we believed it should be valued the same as the CPT code 36223, which was assigned an interim final work RVU of 6.00. Comparable to CPT code 36223, we also believed 30 minutes of postservice time more appropriately accounted for the work of the service and refined the time accordingly. The AMA RUC reviewed the survey results and recommended the survey's median work RVU of 6.50 and a postservice time of 40 minutes for CPT code 36225.

In the CY 2013 final rule (77 FR 69051), we noted that after clinical review of CPT code 36226, we believed it should be valued the same as CPT code 36224, which was assigned work RVU of 6.50. Comparable to CPT code 36224, we believed 30 minutes of postservice time more appropriately accounted for the work of the service. The AMA RUC reviewed the survey results, and after a comparison to similar CPT codes, recommended a value of 7.55 and a postservice time of 40 minutes for CPT code 36226. We assigned a work RVU of 6.50 with refinement to time for CPT code 36226 as interim final for CY 2013.

In the CY 2013 final rule, we noted that after clinical review of CPT code 36227, we determined that efficiencies were gained when services were bundled, and identified a work RVU of 2.09 for the service. A 2.09 work RVU reflected the application of a very conservative estimate of 10 percent for the work efficiencies that we expected to occur when multiple component codes were bundled together to the sum of the work RVUs for the component codes. The AMA RUC reviewed the survey results, and after a comparison to similar CPT codes, recommended a value of 2.32 for CPT code 36227. The AMA RUC used a direct crosswalk to the two component codes being bundled, CPT code 36218, which has a work RVU of 1.01, and CPT code 75660, which has a work RVU of 1.31. We assigned a CY 2013 interim final work RVU of 2.09.

<u>Comment</u>: Commenters stated that the AMA RUC-recommended work RVUs captured all of the efficiencies that were achieved by bundling the services and that our conclusion that these codes values should further be lowered was unsupported and would produce rank order anomalies among intervention

services. Some stated that for CPT codes 36222, 36223, 36224, 36225 and 36226, the AMA RUC-recommended values represented a considerable savings to the Medicare system. Commenters acknowledged that it may be true that efficiencies occur when surgical codes are bundled with other surgical codes or radiologic supervision and interpretation (S&I) codes are bundled with other S&I codes. However, commenters stated that CPT codes 36221 and 36227 reflects the bundling of surgical codes with S&I codes and, that since the activities of surgical codes and S&I codes are, by definition, separate, they disagreed that efficiencies should be assumed. Furthermore, commenters stated that it was incorrect for us to directly crosswalk to other procedures, such as CPT codes 32550, 36251 and 36253, which are easier in nature and entail less risk and less image interpretation, when more parallel crosswalks existed. As such, commenters supported the direct crosswalks and the following recommended work RVUs provided by the AMA RUC: 4.51 for CPT code 36221, 6.00 for CPT code 36222, 6.50 for CPT code 36223, 7.55 for CPT code 36224, 6.50 for CPT code 36225, 7.55 for CPT code 36226 and 2.32 for CPT code 36227 and requested refinement panel review of the codes.

Response: After evaluation of the request for refinement, we determined that the criteria for the request for refinement were not met and, as a result, we did not refer the codes to the CY 2013 multispecialty refinement panel for further review.

After re-review of CPT codes 36221-36227, we maintain that the recommended direct crosswalks for these services are appropriate because the codes involve similar work and, as such, should be valued relative to one another. We also disagree with the commenters that efficiencies do not occur when surgical codes and S&I codes are bundled. Therefore, we are finalizing the CY 2013 interim final values for CY 2014 for CPT codes 36221-36227. We are also finalizing the postservice time refinement of 30 minutes to CPT codes 36221-36226 for CY 2014.

(14) Cardiovascular System: Arteries and Veins (CPT codes 37197 and 37214)

As we noted in the CY 2013 final rule with comment period, we crosswalked the physician time and intensity of CPT code 36247 to CPT code 37197, resulting in a CY 2013 interim final work RVU of 6.29 for CPT code 37197. The AMA RUC had recommended a work RVU of 6.72 for CPT code 37197.

For the CY 2013 final rule with comment period, we assigned an interim final work RVU of 2.74 to CPT code 37214. In making its recommendation, the AMA RUC reviewed the survey results, and after a comparison to similar CPT codes, recommended a work RVU of 3.04 to CPT code 37214. After clinical review, we determined that there were efficiencies gained when services were bundled and ultimately used a very conservative estimate of 10 percent for the work efficiencies we expected to occur when multiple component codes were bundled. Specifically, we decreased the AMA RUC-recommended work RVU value of 3.04 by 10 percent to produce the work RVU value of 2.74, which we assigned as the CY 2103 an interim final work RVU for CPT code 37214.

Comment: Commenters disagreed with these interim final values and suggested that we finalize the AMA RUC-recommended work RVUs of 6.72 for CPT code 37197 and 3.04 for CPT code 37214 because the services are more intense and complex than accounted for by the CY 2013 interim final values. Additionally, several commenters alerted us to our oversight in not providing a written rationale for our work RVU values for CPT codes 37197 and 37214 and as result, requested a technical correction.

Response: The commenters are correct that we did not include a rationale to explain how we reached the interim final work values for these codes in the CY 2013 final rule with comment period. However, Table 30 "Work RVUs for CY 2013 New, Revised and Potentially Misvalued Codes" in the CY 2013 final rule with comment period clearly identified the interim final values being assigned to these codes. It also included the AMA RUC recommendations, denoted whether we agreed with the AMA RUC recommendations, and indicated whether we refined the times recommended by the AMA RUC.

Based upon the comments received, we re-reviewed CPT codes 37197 and 37214. Based upon our review, we believe that directly crosswalking CPT code 37197 to CPT code 36247 and reducing CPT code 37214 by a conservative 10 percent to account for efficiencies gained when services are bundled are appropriate to establish values for these services and produce RVUs that fully reflect the typical work and intensity of the procedures. Therefore, we are finalizing the work RVU of 6.29 for CPT code 37197 and 2.74 for CPT code 37214 for CY 2014.

(15) Hemic and Lymphatic System: General (CPT codes 38240 and 38241)

In the CY 2013 final rule, we noted that after review, we believed CPT code 38240 should have the same work RVU as CPT code 38241 because the two services involved the same amount of work. The AMA RUC recommended a work RVU of 4.00 for CPT code 38240 and 3.00 for CPT code 38241. On an interim final basis for CY 2013 we assigned CPT code 38240 a work RVU of 3.00 and agreed with the AMA RUC recommendation of 3.00 for CPT code 38241.

Comment: Commenters specifically opposed our comparison of work for CPT code 38240 to CPT code 38241, stating that CPT code 38240 was much more complicated, intense and time consuming than CPT code 38241 and, as a result, should have a higher work RVU. Commenters also indicated that CPT 38240 has become more difficult to perform in recent years. Therefore, commenters requested that we use the AMA RUC-recommended work RVU of 4.00 for CPT code 38240 and maintain the interim final value of RVU of 3.00 for CPT code 38241. Commenters asked that both codes be referred to the refinement panel.

Response: After evaluation of the request for refinement, we determined that the criteria for the request for refinement were not met and, as a result, we did not refer CPT codes 38240 and 38241 to the CY 2013 multi-specialty refinement panel for further review.

Based on comments received, we re-reviewed the codes and agree that CPT code 38240 is a more involved and intense procedure than CPT code 38241 and as a result, should have a higher RVU valuation for work than the CY 2013 interim final work RVU. Therefore, we are finalizing the AMA RUC-recommended work RVU for 4.00 to CPT code 38240 and 3.00 for CPT code 38241 for CY 2014.

(16) Digestive System: Lips (CPT code 40490)

As detailed in the CY 2013 final rule with comment period, we assigned an interim final work RVU of 1.22 to CPT code 40490, as recommended by the AMA RUC.

<u>Comment</u>: Commenters agreed and expressed appreciation with our use of the AMA RUC-recommended value.

Response: We are finalizing a work RVU of 1.22 for CPT code 40490 for CY 2014.

(17) Gastrointestinal (GI) Endoscopy (CPT codes 43206 and 43252)

As detailed in the CY 2013 final rule with comment period, CPT codes 43206 and 43252 were contractor priced on an interim final basis. As part of its review of all gastrointestinal endoscopy codes, we received recommendations from the AMA RUC for a work RVU of 2.39 for CPT code 43206 and 3.06 for CPT code 43252. Based upon these recommendations we have the data necessary to establish RVUs and so are assigning CY 2014 interim final work RVUs of 2.39 for CPT code 43206 and 3.06 for CPT code 43252.

As detailed in the CY 2013 final rule with comment period, we assigned an interim final work RVU of 3.20 to CPT code 52287 as recommended by the AMA RUC.

Comment: A specialty association disagreed with our use of the AMA RUC work RVU recommendation for CPT code 52287. The commenter supported the survey's use of CPT code 51715 as the key reference code for this service, but stated that CPT code 52287 should have, at a minimum, the same RVU as CPT code 51715 because CPT code 52287 requires more injections and, as a result, a higher level of technical skill and more time. Therefore, the commenter requested that we accept a work RVU recommendation of 3.79 for CPT code 52287.

Response: After re-review of CPT code 52287, we maintain that our interim final value based upon the AMA RUC recommendation is appropriate. We note that the key reference service CPT code 51715 has more intraservice time (45 minutes) than CPT code 52287 (21 minutes), contrary to the commenter's assertion. We continue to believe that a RVU of 3.20 accurately and fully captures the work required for this service. Therefore, we are finalizing a work RVU of 3.20 for CPT code 52287 for CY 2014.

(19) Urinary System: Bladder (CPT code 52353)

We assigned a CY 2013 interim final work RVU of 7.50 for CPT code 52353. As detailed in the CY 2013 final rule with comment period, after clinical review, we determined that the survey's 25th percentile work RVU represented a more appropriate incremental difference over the base code, CPT code 52351, than the AMA RUC-recommended work RVU of 7.88. Additionally, we believed the survey

25th percentile work RVU more appropriately accounted for the significant reduction in intraservice time from the current value.

<u>Comment</u>: Commenters objected to our reduction in the work RVU from the CY 2012 value and stated that we should use the AMA RUC-recommended work RVU of 7.88. Commenters said that the skills, effort, and time of CPT 52353 were more intense than those of CPT code 52351 and our value did not provide the fully warranted differential between the two codes. Additionally, commenters initially requested refinement panel review of CPT code 52353, but later withdrew their request.

Response: Based on comments received, we re-reviewed CPT code 52353 and continue to believe that our interim final work value is appropriate. We maintain that the survey's 25th percentile work RVU appropriately accounts for the work of this service, especially given the significant reduction in intraservice time and the lack of evidence that .the intensity of this procedure has increased. We also believe that the interim final work value appropriately provides an incremental difference over the base CPT code 52351. For these reasons, we are finalizing a work RVU of 7.50 to CPT code 52353 for CY 2014.

(20) Nervous System: Extracranial Nerves, Peripheral Nerves, and Autonomic Nervous System (CPT code 64615)

The CPT Editorial Panel created CPT code 64615 effective January 1, 2013. The AMA RUC recommended a work RVU of 1.85 and we agreed with the recommendation.

The AMA RUC also requested a decrease in the global period from 10 days to 0 days. As we noted in the CY 2013 final rule, we assigned CPT 64615 a global period of 10 days to maintain consistency within the family of codes.

<u>Comment</u>: Commenters stated that the assigned 10-day global period was not appropriate because there are no E/M post-operative visits related to the service, and accordingly, a 0-day global period would correctly reflect the work involved in, and valuation of, the service. Additionally, commenters noted that the 10-day global period was inconsistent with the 0-day global period we adopted

for other services within the family. Commenters requested that we accept the AMA RUC-recommended global period of 0 days.

Response: Based on comments received, we re-reviewed CPT code 64615 and continue to believe that a 10-day global period is appropriate. Given that most of the other services within this family of CPT codes also have 10-day global periods, we continue to believe that a 10-day global period is appropriate for CPT code 64615. Furthermore, while there are other chemodenerveration codes in other areas of the body that do have 0-day global periods, we continue to believe that a 10-day global period for CPT code 64615 is appropriate in this anatomical region. Therefore, we are finalizing the work RVU of 1.85 for CPT code 64615, with a 10-day global period, for CY 2014.

(21) Eye and Ocular Adnexa: Eyeball (CPT code 65222)

CPT code 65222 was identified as potentially misvalued under the Harvard-valued utilization over 30,000 screen. As we noted in the CY 2013 final rule with comment period, we assigned a work RVU of 0.84 to CPT code 65222, as well as a refinement to the AMA RUC-recommended time. Medicare claims data from 2011 indicated that CPT code 65222 was typically furnished to the beneficiary on the same day as an E/M visit. We believed that some of the activities furnished during the preservice and postservice period overlapped with the E/M visit. We did not believe that the AMA RUC appropriately accounted for this overlap in its recommendation of preservice and postservice time. To account for this overlap, we reduced the AMA RUC-recommended preservice evaluation time by one-third, from 7 minutes to 5 minutes, and the AMA RUC-recommended postservice time by one-third, from 5 minutes to 3 minutes. We believed that 5 minutes of preservice evaluation time and 3 minutes of postservice time accurately reflected the time involved in furnishing the preservice and postservice work of the procedure, and that those times were well-aligned with similar services.

<u>Comment</u>: Commenters disagreed with our work RVU and time refinement for CPT code 65222, stating that they were arbitrary in nature and based on an incorrect assumption that the overlap between the E/M visit and the preservice and postservice periods were not properly accounted for in the AMA RUC recommendation. Commenters stated that the AMA RUC did take the overlap into consideration

and correctly accounted for it through a decrease in the preservice time from the specialty society survey determined time of 13 minutes to 7 minutes. Therefore, commenters requested that we accept the AMA RUC recommendation of a 0.93 work RVU with 7 minutes of preservice time and 5 minutes of postservice time.

Response: Based on comments received, we re-reviewed CPT code 65222 and continue to believe that our interim final work RVU of 0.84 is appropriate. We maintain that the AMA RUC did not fully account for the fact that some of the activities furnished during the preservice and postservice period of the procedure code overlap with those for the E/M visit, making the preservice time reductions recommended by the AMA RUC insufficient. As such, we continue to believe that 5 minutes of preservice evaluation time and 3 minutes of postservice time accurately reflect the physician time involved in furnishing the preservice and postservice work of this procedure, and that these times are well-aligned with similar services. Therefore, we are finalizing a work RVU of 0.84 to CPT code 65222 with 5 minutes of preservice evaluation time and 3 minutes of postservice, for CY 2014.

(22) Eye and Ocular Adnexa: Ocular Adnexa (CPT code 67810)

CPT code 67810 was identified as potentially misvalued under the Harvard-valued utilization over 30,000 screen. On an interim final basis for CY 2013, we assigned the AMA RUC-recommended work RVU of 1.18 to CPT code 67810, with a refinement to the AMA RUC-recommended time. As we noted in the CY 2013 final rule with comment period, Medicare claims data from CY 2011 indicated that CPT code 67810 was typically furnished to the beneficiary on the same day as an E/M visit. We noted that that some of the activities furnished during the preservice and postservice period of the procedure code and the E/M visit overlapped and that although the AMA RUC appropriately accounted for this overlap in its recommendation of preservice time, its recommendation for postservice time was high relative to similar services performed on the same day as an E/M service. To better account for the overlap in the postservice period, and to value the service relative to similar services, we reduced the AMA RUC-recommended postservice time for this procedure by one-third, from 5 minutes to 3 minutes.

Comment: Commenters believed that our time refinement for CPT code 67810 was unsubstantiated and that we were incorrect in assuming that the overlap between the E/M visit and the postservice period was not appropriately accounted for in the AMA RUC recommendation. Commenters suggested that the AMA RUC did take the overlap into consideration and appropriately accounted for it by lowering the time recommendations by nearly 50 percent. Therefore, commenters requested that we accept the AMA RUC-recommended postservice time of 5 minutes for CPT code 67810.

Response: Based on comments received, we re-reviewed CPT code 67810 and continue to believe that our interim final work RVU of 1.18 and our time refinement is appropriate. We maintain that the AMA RUC did not fully account for the fact that some of the activities furnished during the postservice period of the procedure code overlap with the E/M visit and that the AMA RUC's time refinements were insufficient. As such, we continue to believe that 3 minutes of postservice time accurately reflects the physician time involved in furnishing the postservice work of this procedure, and that this time is well-aligned with that for similar services. Therefore, we are finalizing a work RVU of 1.18 to CPT code 67810 with 3 minutes of postservice time for CY 2014.

(23) Eye and Ocular Adnexa: Conjunctiva (CPT code 68200)

CPT code 68200 was identified as potentially misvalued under the Harvard-valued utilization over 30,000 screen. On an interim final basis for CY 2013, we assigned a work RVU of 0.49 to CPT code 68200, with a refinement to the AMA RUC-recommended time. As we noted in the CY 2013 final rule with comment period, Medicare claims data from CY 2011 indicated that CPT code 68200 was typically furnished to the beneficiary on the same day as an E/M visit. We believed that some of the activities furnished during the preservice and postservice period of the procedure code overlapped with the E/M visit. We believed that the AMA RUC appropriately accounted for this overlap in its recommendation of preservice time, but did not adequately account for the overlap in the postservice time. To better account for the overlap in postservice time, we reduced the AMA RUC-recommended postservice time for this procedure by one-third, from 5 minutes to 3 minutes. After reviewing CPT code 68200 and assessing the overlap in time and work, we agreed with the AMA RUC-recommended work RVU of 0.49 for CY 2013.

Comment: Commenters believed that our time refinement for CPT code 68200 was unsupported and that we assumed incorrectly that the overlap between the E/M visit and the postservice period was not appropriately accounted for in the AMA RUC recommendation. Commenters suggested that the AMA RUC did take the overlap into consideration and completely accounted for it by lowering the preservice time recommendation. Therefore, commenters request that we accept the AMA RUC-recommended postservice time of 5 minutes postservice for CPT code 68200.

Response: After reviewing the comments, we continue to believe that our refinement of the recommended time is appropriate. We maintain that the AMA RUC did not fully account for the fact that some of the activities furnished during the postservice period of the procedure code overlap with the E/M visit and that the AMA RUC-recommended time refinements were insufficient. As such, we continue to believe that 3 minutes of postservice time accurately reflects the time involved in furnishing the postservice work of this procedure, and that this time is well-aligned with similar services. Therefore, we are finalizing a work RVU of 0.49 for CPT code 68200 with 3 minutes of postservice time, for CY 2014.

CPT code 69200 was identified as potentially misvalued under the Harvard-valued utilization over 30,000 screen. On an interim final basis for CY 2013, we assigned a work RVU of 0.77 to CPT code 69200, as well as refining to the AMA RUC-recommended time. In the CY 2013 final rule, we noted that Medicare claims data from 2011 indicated that CPT code 69200 was typically furnished to the beneficiary on the same day as an E/M visit and that some of the activities furnished during the preservice and postservice period of the procedure code overlapped with the E/M visit. To account for this overlap, we removed one-third of the preservice evaluation time from the preservice time package, reducing the preservice evaluation time from 7 minutes to 5 minutes. Additionally, we reduced the AMA RUC-recommended postservice time for this procedure by one-third, from 5 minutes to 3 minutes. After reviewing CPT code 69200 and assessing the overlap in time and work, we agreed with the AMA RUC-recommended work RVU of 0.77 for CY 2013.

<u>Comment</u>: A commenter thanked us for our acceptance of the AMA RUC-recommended work for CPT code 69200.

Response: For CY 2014, we are finalizing the interim final work RVU and time for this code.

(25) Eye and Ocular Adnexa: Conjunctiva (CPT code 69433)

As detailed in the CY 2013 final rule with comment period, we assigned an interim final work RVU of 1.57 to CPT code 69433; which the AMA RUC had recommended.

<u>Comment</u>: A commenter thanked us for our acceptance of the AMA RUC recommendation.

Response: We are finalizing our interim final work RVU for CY 2014.

(26) Computed Tomographic (CT) Angiography (CPT code 72191)

As detailed in the CY 2013 final rule with comment period, CPT code 72191 was assigned a CY 2013 interim final work RVU of 1.81, consistent with the AMA RUC recommendation.

As detailed in this final rule with comment period, based upon the AMA RUC recommendations, we are establishing interim final values for codes within the CT angiography family. To allow for contemporaneous public comment on this entire family of codes, we are maintaining the CY 2013 work value for CPT code 72191 as interim final for CY 2014.

(27) Radiologic Guidance: Fluoroscopic Guidance (CPT codes 77001, 77002 and 77003)

As detailed in the CY 2013 final rule with comment period, CPT codes 77001, 77002 and 77003 were assigned CY 2013 interim final work RVUs of 0.38, 0.54 and 0.60, respectively, based upon AMA RUC recommendations. We received AMA RUC recommendations for work RVUs of 0.38 for CPT code 77001, 0.54 for CPT code 77002 and 0.60 for CPT code 77003.

We agree with the AMA RUC-recommended values but are concerned that the recommended intraservice times for all three codes are generally higher than the procedure codes with which they are typically billed. For example, CPT code 77002 has 15 minutes of intraservice time and CPT code 20610 (Arthrocentesis, aspiration and/or injection; major joint or bursa (eg, shoulder, hip, knee joint, subacromial bursa)) has an intraservice time of only 5 minutes. We are requesting additional public comment and input from the AMA RUC and other stakeholders regarding the appropriate relationship

between the intraservice time associated with fluoroscopic guidance and the intraservice time of the procedure codes with which they are typically billed. Therefore, for CY 2014 we are assigning CY 2014 interim final work RVUs of 0.38 to CPT code 77001, 0.54 to CPT code 77002 and 0.60 to CPT code 77003.

(28) Radiology (CPT codes 75896 and 75898)

CPT code 75896 was identified as potentially misvalued through the codes reported together 75 percent or more screen. As we noted in the CY 2013 final rule with comment period, the AMA RUC intended to survey and review CPT codes 75896 and 75898 for CY 2014 as part of their work on bundling thrombolysis codes. The AMA RUC recommended contractor pricing these two services for CY 2014. However, since we had established a national payment rate for the professional component of these services and only the technical component of the services was contractor priced at that time, we maintained the national price on the professional component and continued contractor pricing for the technical component for these codes on an interim final basis for CY 2013.

We did not receive any comments on these codes nor did we receive any recommendations from the AMA RUC. As we anticipate receiving AMA RUC recommendations for these codes, we are maintaining the current pricing on an interim final basis for CY 2014.

(29) Pathology (CPT codes 88120, 88121, 88365, 88367, and 88368)

The CPT Editorial Panel created CPT 88120 and 88121 effective for CY 2011. In the CY 2012 PFS final rule with comment period, we assigned interim final work RVUs of 1.20 and 1.00 to CPT codes 88120 and 88121, respectively. We maintained the 2012 work RVUs for 88120 and 88121 as interim final for CY 2013. Additionally, we expressed concern about potential payment disparities between these codes and similar codes, CPT codes 88365, 88367 and 88368, and asked the AMA RUC to review the work and PE for these codes to ensure the appropriate relativity between the two sets of services. Since the AMA RUC is reviewing CPT codes 88365, 88367, and 88368, we are establishing CY 2014 interim final work RVUs of 1.20 for CPT code 88365, 1.30 for CPT code 88367, and 1.40 for CPT code 88368 for CY 2014.

<u>Comment</u>: A commenter stated that it was appropriate to reaffirm the values for 88120 and 88121.

Response: For the reasons stated above, we are assigning CY 2014 interim final work RVUs of 1.20 and 1.00 to CPT codes 88120 and 88121, respectively.

(30) Optical Endomicroscopy (CPT Code 88375)

As detailed in the CY 2013 final rule with comment period, CPT code 88375 was assigned an interim final PFS procedure status of C (Contractors price the code. Contractors establish RVUs and payment amounts for these services.). We received a recommendation from the AMA RUC for a work RVU of 1.08 for CPT code 88375.

CPT code 88375 provides a code for reporting the pathology service when one is required to assist in the procedure. The AMA RUC recommended an intraservice time of 25 minutes and a work RVU of 1.08 for CPT code 88375. Based on our analysis of this recommendation, we believe that the typical optical endomicroscopy case will involve only the endoscopist, and CPT codes 43206 and 43253 are valued to reflect this. Accordingly, we believe a separate payment for CPT code 88375 would result in double payment for a portion of the overall optical endomicroscopy service. Therefore, we are assigning a PFS procedure status of I (Not valid for Medicare purposes. Medicare uses another code for the reporting of and the payment for these services) to CPT code 88375. In the unusual situation that a pathologist is requested to assist an endoscopist in optical endomicroscopy, we would expect the pathologist to report other codes more appropriate to the service (e.g. CPT code 88392 Pathology consultation during surgery).

(31) Psychiatry (CPT codes 90785, 90791, 90792, 90832, 90833, 90834, 90836, 90837, 90838, 90839, 90840, 90845, 90846, 90847, 90853 and 90863)

For CY 2013, the CPT Editorial Panel restructured the psychiatry/psychotherapy CPT codes allowing for separate reporting of E/M codes, eliminating the site-of-service differential, creating codes for crisis, and creating a series of add-on psychotherapy codes to describe interactive complexity and medication management. The AMA RUC recommended values for all of the codes in this family except

CPT codes 90785 (add-on for interactive complexity), 90839 (psychotherapy for crisis, first 60 minutes), 90840 (each additional 30 minutes) and 90863 (pharmacologic management, when performed with psychotherapy) which were the AMA RUC recommended to be contractor priced. In establishing CY 2013 values for the psychitry codes, our general approach was to maintain the CY 2012 values for the services or adopt values that approximated the CY 2012 values after adjusting for differences in code structure between CY 2012 and 2013, for all psychiatry/psychotherapy services on an interim final basis. We noted in the CY 2013 final rule with comment period that we intended to review the values for all the codes in the family once the survey process was complete and we had recommendations for all the codes. This would allow for a comprehensive review of the values for the full code set that would ensure more accurate valuation and proper relativity. The CY 2013 interim values for this family can be found in Table 24.

We have now received AMA RUC recommendations for all of the codes in the family and are establishing CY 2014 interim final work RVUs based on these recommendations. The CY 2014 interim work values displayed in Table 24 correspond with the AMA RUC recommended values, with the exception of CPT code 90863, which has been assigned a PFS procedure status of I (Not valid for Medicare purposes. Medicare uses another code for the reporting of and the payment for these services). These recommendations, which are now complete, have provided us with a comprehensive set of information regarding revisions to the overall relative resource costs for these services. This is consistent with the approach we described in the CY 2013 PFS final rule with comment period (77 FR 69060 – 69063). Because of the changes for this relativity new code set, we are establishing these values on an interim final basis.

Comment: Several commenters urged CMS to use the AMA RUC-recommended values for CY 2013 and questioned why CMS chose instead to adopt a general approach of maintaining the CY 2012 values for the services. These commenters noted that CMS has previously adopted interim final values for only a portion of new codes in a family, pending subsequent valuation of other codes in the family. Other commenters questioned the logic of maintaining preexisting values for these services since the new

set of codes resulted from the identification of these services as potentially misvalued several years ago. Other commenters pointed out that the general approach to valuing the codes resulted in anomalous values. Several other commenters suggested alternative work values for the codes with and without corresponding AMA RUC recommendations.

Response: We appreciate commenters' concerns regarding the appropriate valuation of this family of codes. We also acknowledge that commenters accurately point out that, in some cases, we have previously established new interim values for new codes when related codes have not been simultaneously reviewed. However, as we explained in the CY 2013 final rule with comment period (77 FR 69060), the CY 2013 changes for this family of codes consisted of a new structure that allowed for the separate reporting of E/M codes, the elimination of the site-of-service differential, the establishment of CPT codes for crisis, and the creation of a series of add-on CPT codes to psychotherapy to describe interactive complexity and medication management. We believed that the unusual complexity of these coding changes and the magnitude of their impacts among the affected specialties that furnish these services necessitated a comprehensive review of the potential impact of the changes prior to adopting significant changes in overall value. We also acknowledge that maintaining overall value for services between calendar years with coding changes presents extensive challenges that often result in anomalous values between individual codes. Since we are establishing new interim final work RVUs for the codes in this family for CY 2014 based on the recommendations of the AMA RUC, we believe that commenters' concerns regarding our approach to CY 2013 have been largely been mitigated for CY 2014. We note that the interim final CY 2014 work RVUs for all of these services are open for comment and we will respond to comments regarding these values in the CY 2015 PFS final rule with comment period.

<u>Comment</u>: Several commenters stated that it was difficult for health care professionals that furnish these services to implement use of the new CPT codes for Medicare payment with only a few months' notice given the technology involved in claims systems. Other commenters suggested that CMS should revise CPT code descriptors for codes to conform to Medicare policies.

Response: We appreciate the concern regarding insufficient time to adopt new codes. Although we would prefer for the new, revised and deleted codes to be released in time to appear in PFS proposed rulemaking, the timing of the annual release of the new codes set is completely under the control of the CPT Editorial Panel. We note that CMS does not have the authority to alter CPT code descriptors.

<u>Comment</u>: Several commenters supported CMS's decision to assign CPT code 90863 with a PFS procedure status indicator of I (Not valid for Medicare purposes. Medicare uses another code for the reporting of and the payment for these services) for CY 2013 and encouraged CMS to maintain that status for CY 2014.

Response: We appreciate commenters' support for this assignment. We understand from our past meetings with stakeholders that the ability to prescribe medicine is predicated upon first providing evaluation and management (E/M) services. Although clinical psychologists have been granted prescriptive privileges in Louisiana and New Mexico, we do not believe that they are n authorized under their state scope of practice to furnish the full range of traditional E/M services. As a result, we believe that clinical psychologists continue to be precluded from billing Medicare for pharmacologic management services under CPT code 90863 because pharmacologic management services require some knowledge and ability to furnish E/M services, as some stakeholders have indicated. Even though clinical psychologists in Louisiana and New Mexico have been granted prescriptive privileges, clinical psychologists overall remain unlicensed and unauthorized by their state to furnish E/M services.

Accordingly, on an interim final basis for CY 2014, for CPT code 90863, we are maintaining a PFS procedure status indicator of I (Not valid for Medicare purposes. Medicare uses another code for the reporting of and the payment for these services.).

(32) Cardiovascular: Therapeutic Services and Procedures (CPT codes 92920, 92921, 92924, 92925, 92928, and 92929)

The CPT Editorial Panel created 13 new percutaneous coronary intervention (PCI) CPT codes for CY 2013 (92920, 92921, 92924, 92925, 92928, 92929, 92933, 92934, 92937, 92938, 92941, 92943, and 92944) to replace the 6 existing codes, which resulted in a greater level of granularity.

As detailed in the CY 2013 final rule with comment period, we believed that the CPT-established unbundling of the placement of branch-level stents may encourage increased placement of stents. To eliminate that incentive, on an interim final basis for CY 2013, we rebundled the work associated with the placement of a stent in an arterial branch into the base code for the placement of a stent in an artery. Accordingly, for CY 2013 we bundled each new add-on code into its base code. Specifically, we bundled the work of CPT code 92921 into CPT code 92920, the work of CPT code 92925 into CPT code 92924, the work of CPT code 92929 into CPT code 92933, the work of CPT code 92938 into CPT code 92937; and the work of CPT code 92944 into CPT code 92943.

In the CY 2013 final rule with comment period we explained how we established the work RVUs for the new bundled codes. For each code, we used the AMA RUC-recommended utilization crosswalk to determine what percentage of the base code utilization would be billed with the add-on code, and added that percentage of the AMA RUC-recommended work RVU for the add-on code to the AMA RUC-recommended work RVU for the base code. Based on this methodology, we assigned the following CY 2013 interim final work RVUs: 10.10 to CPT code 92920, 11.99 to CPT code 92924, 11.21 to CPT code 92928, 12.54 to CPT code 92933, 11.20 to CPT code 92937, and 12.56 to CPT code 92943.

On an interim final basis for CY 2013, add-on CPT codes 92921, 92925, 92929, 92934, 92938, and 92944 were assigned a PFS procedure status indicator of B (Bundled code. Payments for covered services are always bundled into payment for other services, which are not specified. If RVUs are shown, they are not used for Medicare payment. If these services are covered, payment for them is subsumed by the payment for the services to which they are bundled.) Therefore, these codes were not separately payable.

As detailed in the CY 2013 final rule with comment period, we did not use this methodology to establish a work RVU for CPT code 92941, which did not have a specific corresponding add-on code. After reviewing the service alongside the other services in the family, we believed CPT code 92941 had the same work as CPT code 92943. As we stated above, we assigned a work RVU of 12.56 to CPT code

92943. Therefore, on an interim final basis for CY 2013 we assigned a work RVU of 12.56 to CPT code 92941 with the AMA RUC-recommended intraservice time of 70 minutes.

Commenters: Commenters disagreed with our bundling of codes into their respective base codes.

Commenters stated that we negated the work of the CPT Editorial Panel, specialty societies, and the AMA RUC by further bundling already bundled codes for PCI services. They indicated that the additional bundling of payment for these codes generated a substantial disconnect between the coding guidelines detailed in the CPT manual and the use of the codes under the Medicare system, causing great uncertainty and confusion. Additionally, commenters stated that the decreases in PCI were of serious concern because it would drive physicians from private practice. Therefore, commenters requested we adopt the CPT Editorial Panel coding construct and the AMA RUC-recommended values for all of the PCI codes. Furthermore, commenters requested that we publish the values for the bundled codes, even though they were not recognized for separate payment by Medicare, so that third-party carriers who depend on the PFS to determine payment rates can develop payment policies that conform to the CPT Editorial Panel's coding decisions.

Response: After re-review, we maintain that our valuation and bundling of codes into their respective base codes is appropriate. We continue to believe that the revised CPT coding structure represents a trend toward creating greater granularity in codes that describe the most intense and difficult work. Specifically for this code family, we continue to believe that making separate Medicare payment for unbundled codes that describe the placement of branch-level stents may encourage increased placement of stents in a fee-for-service system. To eliminate that incentive while maintaining an appropriate reflection of the resources involved in furnishing these services, we continue to believe that rebundling the work associated with the placement of a stent in an arterial branch into the base code for the placement of a stent in an artery is appropriate and consistent with the prior coding structure.

Therefore, we are finalizing work RVU values of 10.10 for CPT code 92920, 11.99 for CPT code 92924 and 11.21 for CPT 92928 and a PFS procedure status indicator of B (Bundled code. Payments for covered services are always bundled into payment for other services, which are not specified. If RVUs

are shown, they are not used for Medicare payment. If these services are covered, payment for them is subsumed by the payment for the services to which they are bundled for CPT codes 92921, 92925 and 92929 for CY 2014. We are also finalizing for CY 2014 a work RVU of 12.56 for CPT code 92941, with the AMA RUC-recommended intraservice time of 70 minutes.

(33) Cardiovascular: Intracardiac Electrophysiological Procedures/Studies (CPT codes 93655 and 93657)

Previously, CPT codes 93651 and 93652 were identified as potentially misvalued through the codes reported together 75 percent or more screen. Upon reviewing these codes, the CPT Editorial Panel deleted CPT codes 93651 and 93652 and and replaced them with new CPT codes 93653 through 93657 effective January 1, 2013.

As detailed in CY 2013 final rule with comment period, we believed these codes had a similar level of intensity to CPT codes 93653, 93654, and 93656, which were all valued at 5.00 RVUs per 1 hour of intraservice time. Therefore, for CY 2013 we assigned a work RVU of 7.50 to CPT codes 93655 and 93657, which have 90 minutes of intraservice time. The AMA RUC recommended a work RVU of 9.00 for CPT code 93655 and a work RVU of 10.00 for CPT code 93657.

Comment: Commenters disagreed with the incremental value methodology for CPT codes 93655 and 93657, stating that our approach did not accurately account for the intensity of these services. They stated that CPT codes 93655 and 93657 are more intense and complex procedures than CPT codes 93653, 93654, and 93656 because patients who require the services have widespread refractory disease, requiring additional technical skill and time. Therefore, commenters requested we use the AMA RUC-recommended work RVUs of 9.0 for CPT code 93655 and 10.0 for CPT code 93657. In addition, one commenter requested that we refer these codes to the refinement panel.

Response: After reviewing the request for refinement, we agreed that CPT codes 93655 and 93657 met the requirements for refinement and referred the codes to the CY 2013 multi-specialty refinement panel for further review. The refinement panel median work RVU for CPT codes 93655 and 93657 are 9.00, and 10.00 respectively. Following the refinement panel meeting, we again reviewed the work involved in this code and continue to believe that the two services involve a very similar level of

intensity to CPT codes 93653, 93654, and 93656, which are all valued at 5.00 RVUs per 1 hour of intraservice time. We continue to believe that this is the appropriate value for CPT codes 93655 and 93657 because we believe these services contain the same amount of work as the base codes, CPT codes 93653, 93654, and 93656. Therefore, we are finalizing a work RVU of 7.50 for CPT codes 93655 and 93657 for CY 2014.

(34) Noninvasive Vascular Diagnostic Studies: Extremity Arterial Studies (Including Digits) (CPT codes 93925 and 93926)

Previously, CPT codes 93925 and 93926 were identified by the AMA RUC as potentially misvalued and we received AMA RUC recommendations for CY 2013.

After reviewing CPT codes 93925 and 93926, we believed that the survey's 25th percentile work RVUs of 0.80 for CPT code 93925 and 0.50 for CPT code 93926 accurately accounted for the work involved in furnishing the services and appropriately captured the increase in work since the services were last valued and assigned these as interim final work RVUs for CY 2013. As we noted in the CY 2013 final rule with comment period, we believed that the AMA RUC-recommended survey median work RVUs of 0.90 for CPT code 93925 and 0.70 for CPT code 93926 overstated the increase in work for the services and that the RVUs were too high relative to similar services. Regarding physician time, we refined the AMA RUC-recommended preservice and postservice times from 5 minutes to 3 minutes to align with similar services, specifically CPT codes 93922 and 93923.

Comment: All commenters disagreed with our work valuation and some commenters also disagreed with our time refinements for CPT codes 93925 and 93926. One commenter stated that the work RVUs for CPT codes 93925 and 93926 should be increased because the work associated with the services has changed and also argued that our valuations were arbitrary in nature and unsupported. Two commenters noted that the AMA RUC-recommended work RVUs of 0.90 for CPT code 93925 and 0.70 for CPT code 93926 were supported by relativity comparisons to CPT codes 93306, 73700, 76776 and 76817 and according the CY 2013 interim final work RVU values were too low. Additionally, two commenters disagreed with our time refinements for CPT codes 93925 and 93926 from the survey's

median to the survey's 25th percentile values. One commenter specifically disagreed with our use of CPT codes 93922 and 93923 as reference codes for time refinements because they stated "physiologic studies do not require artery-by-artery inch-by-inch assessment of femoral and tibial arteries, as do the duplex exams" and as such, are not appropriate codes for comparison. They added that CPT codes 93925 and 93926 require more time for proper performance of the exam and interpretation of results. All commenters suggested acceptance of the AMA RUC recommendations. One commenter also requested refinement panel review of the codes.

Response: After evaluation of the request for refinement, we determined that the criteria for the request for refinement were not met and, as a result, we did not refer CPT codes 93925 and 93926 to the CY 2013 multi-specialty refinement panel for further review.

After reviewing the comments, we maintain that our valuation is appropriate. We continue to believe that that the survey's 25th percentile work RVUs of 0.80 for CPT code 93925, and 0.50 for CPT code 93926 accurately account for the work involved in furnishing these services and appropriately captures the increase in work since these services were last valued. Additionally, we continue to believe that a refinement to the AMA RUC-recommended time is appropriate to align the times with those associated with CPT codes 93922 and 93923 that describe similar services. Therefore, we are finalizing a work RVU of 0.80 to CPT code 93925 and a work RVU of 0.50 to CPT code 93926, with 3 minutes of preservice and postservice time for CY 2014.

(35) Neurology and Neuromuscular Procedures: Sleep Medicine Testing CPT codes 95782 and 95783)

The CPT Editorial Panel created new CPT codes 95782 and 95783, effective January 1, 2013, to describe the work involved in pediatric polysomnography for children 5 years of age or younger. For CY 2013, we assigned an interim final work RVU of 2.60 to CPT code 95782 and a work RVU of 2.83 to CPT code 95783. As we noted in the CY 2013 final rule with comment period, we assigned these values after we reviewed CPT codes 95782 and 95783 and determined that the survey's 25th percentile work RVUs of 2.60 for CPT code 95782 and 2.83 for CPT code 95783 appropriately reflected the work

involved in furnishing the services. The AMA RUC recommended the survey's median work RVUs of 3.00 for CPT code 95782 and 3.20 for CPT code 95783.

Comment: Commenters disagreed with our valuation of CPT codes 95782 and 95783, stating that the services should have received a greater valuation explaining that it is more difficult to perform sleep studies on children than adults, and more work is required to obtain an accurate polysomnogram due to children's greater need for attention and, in some cases, even mild sedation. Additionally, commenters noted that the work involved in the interpretation of data supported a higher work RVU. Therefore, commenters requested that we use the AMA RUC-recommended work RVU of 3.00 for CPT code 95782 and 3.20 for CPT code 95783.

Response: After consideration of comments and re-reviewing of CPT codes 95782 and 95783, we maintain that our valuation is appropriate. We continue to believe that that the survey's 25th percentile work RVUs of 2.60 for CPT code 95782 and 2.83 for CPT code 95783 accurately accounts for the work involved in furnishing these services. Therefore, we are finalizing a work RVU of 2.60 for CPT code 95782 and 2.83 for CPT code 95783, for CY 2014.

(36) Neurology and Neuromuscular Procedures: Electromyography and Nerve Conduction Tests (CPT codes 95885, 95886, and 95887)

CPT codes 95860, 95861, 95863, and 95864 were previously identified as potentially misvalued through the codes reported together 75 percent or more screen. The relevant specialty societies submitted a code change proposal to the CPT Editorial Panel to bundle the services commonly reported together. In response, the CPT created three add-on codes (CPT codes 95885, 95886, and 95887) and seven new codes (CPT codes 95907 through 95913) that bundled the work of multiple nerve conduction studies into each individual code.

We agreed with the AMA RUC recommendation for CPT code 95885 and assigned a CY 2013 interim final work RVU of 0.35. After review, we determined that CPT codes 95886 and 95887 involved the same level of work intensity as CPT code 95885. To determine the appropriate RVU for CPT codes 95886 and 95887, we increased the work RVUs of CPT codes 95886 and 95887 proportionate to the

differences in times from CPT code 95885. Therefore, we assigned an interim final work RVU of 0.70 to CPT code 95886 and of 0.47 to CPT code 95887 for CY 2013 as compared to the AMA RUC-recommended 0.92 and 0.73, respectively.

Comment: Commenters indicated that we utilized a flawed building block approach in valuing CPT codes 95886 and 95887 because the methodology did not take into account precise distinctions within each service and inaccurately assumed that the codes had identical intensity and complexity. Commenters supported the AMA RUC-recommended values developed using magnitude estimation saying that the methodology was more precise due to its use of data derived from multiple factors like physician time, intensity and work value estimates. Additionally, commenters noted that we failed to distinguish the increasing intensity and complexity involved as additional nerve conductions were performed. Therefore, commenters requested our use of the AMA RUC-recommended work RVU of 0.92 for CPT code 95886 and 0.73 for CPT code 95887 and refinement panel review of the codes.

Response: After reviewing the request for refinement, we agreed that CPT codes 95886 and 95887 met the requirements for refinement and referred the codes to the CY 2013 multi-specialty refinement panel for further review. The refinement panel median work RVUs for CPT codes 95886 and 95887 were respectively, 0.92 and 0.73. Following the refinement panel meeting, we again reviewed the work involved in these codes and agreed with the panel that these codes were more intense and complex than reflected in the CY 2013 interim final values and, as such, warranted a higher work RVU. While we agree that work RVUs for CPT codes 95886 and 95887 should be increased, based on our clinical review, we conclude that the refinement panel's suggested values overstate the work involved in these procedures.

We believe that the work for CPT code 95886 is similar to the work performed when five or more muscles are examined in one extremity, as described by CPT code 95860, which has a work RVU of 0.96. However, CPT code 95886 is an add-on code to nerve conduction studies. Therefore, as we have previously valued services that overlap with another CPT code, we applied a 10% reduction to the work RVU of CPT code 95860 to determine a work RVU of 0.86 for CPT code 95886. Similarly, in our

valuation of CPT code 95887, we believe that the work for the code is similar to the work performed when cranial nerve supplied muscles are examined, as described by CPT code 95867, which has a work RVU of 0.79. However, CPT code 95887 is an add-on code to nerve conduction studies. Therefore, as we have previously valued services that overlap with another code, we applied a 10 percent reduction to the work RVU of CPT code 95867 to determine a work RVU of 0.79 for CPT code 95887. For CY 2014, we are finalizing a work RVU of 0.86 for CPT code 95886 and 0.71 for CPT code 95887.

(37) Neurology and Neuromuscular Procedures: Electromyography and Nerve Conduction Tests (CPT codes 95908, 95909, 95910, 95911, 95912, and 95913)

In our CY 2013 review, we did not accept the AMA RUC-recommended values for CPT codes 95908, 95909, 95910, 95911, 95912, and 95913. For those codes, we found that the progression of the survey's 25th percentile work RVUs and survey's median times appropriately reflected the relativity of the services and valued the codes accordingly. CPT code 95908 was an exception to this, as we believed the survey's 25th percentile work RVU was too low relative to other fee schedule services. Therefore, we assigned the following work RVUs for CY 2013: 1.00 to CPT code 95907, 1.25 to CPT code 95908, 1.50 to CPT code 95909, 2.00 to CPT code 95910, 2.50 to CPT code 95911, 3.00 to CPT code 95912, and 3.56 to CPT code 95913.

Additionally, we refined the AMA RUC-recommended intraservice time for CPT code 95908 from 25 minutes to the survey's median time of 22 minutes and for CPT code 95909 from 35 minutes to the survey's median time of 30 minutes, so that all the CPT codes in the series were valued using the survey's median intraservice time.

Comment: Commenters disagreed with our valuation of CPT codes 95908, 95909, 95910, 95911, 95912, and 95913. Commenters opposed the interim final values for the codes because they believed the intensity and complexity of the procedures increased as more nerve conductions were performed and as a result, believed that the valuations should be higher. Additionally, commenters believe that because no significant changes in the efficiencies of the test had occurred, in terms of time and cost related to performance, that our changes in the valuations were unjustified. Therefore, commenters requested that

we accept the AMA RUC-recommended work RVUs for all of these codes and requested refinement panel review. Lastly, commenters also suggested that if the interim final values were to be finalized, that their implementation be staggered to limit the adverse impacts that the values would have on health care access.

Response: After reviewing the request for refinement, we agreed that CPT codes 95908, 95909, 95910, 95911, 95912, and 95913 met the requirements for refinement and referred the codes to the CY 2013 multi-specialty refinement panel for further review. The refinement panel median work RVUs were: 1.37 for CPT code 95908, 1.77 for CPT code 95909, 2.80 for CPT code 95910, 3.34 for CPT code 95911, 4.00 for CPT code 95912, and 4.20 for CPT code 95913. Following the refinement panel meeting, we again reviewed the work involved in these codes and continue to believe that the progression of the survey's 25th percentile work RVUs and survey median times for these codes appropriately reflect the relativity of these codes. CPT code 95908 was an exception to this approach because we believe that the survey's 25th percentile work RVU is too low relative to other fee schedule services. We also note that we do not believe that the results of the survey support the notion that the intensity and complexity of the procedures increases as more nerve conductions are performed. Instead, we believe that the incremental differences reflected in the survey correspond with the incremental differences in our CY 2013 interim final values. Therefore, we are finalizing the CY 2013 interim final work RVUs and time refinements for CPT codes 95908, 95909, 95910, 95911, 95912, and 95913 for CY 2014. With regard to the comment that our rates would impede access to these critical services, we are unaware of data that shows that access has declined.

(38) Evoked Potentials (CPT codes 95928 and 95929)

As detailed in the CY 2013 final rule with comment period, CPT codes 95928 and 95929 were each assigned a CY 2013 interim final work RVU of 1.50. Subsequently, the AMA RUC recommended intraservice time for these codes based on only 19 of the 28 survey responses. As a result, the AMA RUC recommendations included an intraservice time of 40 minutes with which we do not agree. When based on all 28 survey responses, the intraservice time is 33 minutes. We agree with the AMA RUC

recommended preservice and postservice times because they are consistent across all 28 survey responses. Therefore, for CY 2014, we are refining the preservice time, intraservice and postservice times for CPT codes 95928 and 95929 to 15 minutes, 33 minutes and 10 minutes, respectively. We are assigning CY 2014 interim final work RVUs of 1.50 to CPT codes 95928 and 95929, based upon the AMA RUC recommendations, and are seeking public input on the time of the codes.

(39) Neurology and Neuromuscular Procedures: Intraoperative Neurophysiology (CPT codes 95940 and 95941 and HCPCS code G0453)

Effective January 1, 2013, the CPT Editorial Panel deleted CPT code 95920 and replaced it with CPT codes 95940 for continuous intraoperative neurophysiology monitoring in the operating room requiring personal attendance and 95941 for continuous intraoperative neurophysiology monitoring from outside the operating room (remote or nearby). Prior to CY 2013, the Medicare PFS paid for remote monitoring billed under CPT code 95920, which was used for both in-person and remote monitoring. For CY 2013, we created HCPCS code G0453 to be used for Medicare purposes instead of CPT code 95941. Unlike CPT code 95941, HCPCS code G0453 can be billed only for undivided attention by the monitoring physician to a single beneficiary, not for the monitoring of multiple beneficiaries simultaneously. Since G0453 was used for remote monitoring of Medicare beneficiaries, CPT code 95941 was assigned a PFS procedure status indicator of I (Not valid for Medicare purposes. Medicare uses another code for the reporting of and the payment for these services.

As detailed in the CY 2013 final rule with comment period, after reviewing CPT code 95940, we agreed with the AMA RUC that a work RVU of 0.60 accurately accounted for the work involved in furnishing the procedure. Also, we agreed with the AMA RUC that a work RVU of 2.00 accurately accounted for the work involved in furnishing 60 minutes of continuous intraoperative neurophysiology monitoring from outside the operating room. Accordingly, we assigned a work RVU of 0.50 to HCPCS code G0453, which described 15 minutes of monitoring from outside the operating room, on an interim final basis for CY 2013.

Commenters Commenters disagreed with our valuation of CPT codes 95940, 95941 and G0453.

Commenters opposed the one-on-one patient to physician model that our recommendations proposed.

Commenters stated the following: G0453 was contradictory to current provider models; the accessibility of IONM services would be lowered; surgeons would be deprived of advantageous services; qualified level of professional supervision would be reduced; hospitals would suffer increased overheard costs; and GO453 inappropriately assessed the services. Therefore, commenters requested we withdraw HCPCS code G0453 and validate CPT codes 95940 and 95941 together, through acceptance of the AMA RUC-recommended work RVUs of 0.60 for CPT code 95940 and 2.00 for CPT code 95941.

Another commenter suggested we value CPT code 95941 at 0.5 of CPT 95940 although a rationale for that valuation was not provided. Several other commenters requested we increase the work value of G0453 so that it was equal to the work RVU assigned to CPT code 95940 because they believed the physician time and effort for both services was the same. The majority of commenters suggested we value the concurrent monitoring of up to 4 patients by a neurologist with the creation of additional G codes for the remote monitoring of 2, 3 or 4 patients.

Response: Based on comments received, we re-reviewed CPT codes 95940, 95941 and HCPCS code G0453 and agree that based on the comparable nature of the work between CPT code 95940 and HCPCS code G0453, that G0453 should be valued equally to CPT code 95940.

Therefore, we are finalizing a work RVU of 0.60 to CPT code 95940 and 0.60 to HCPCS code G0453 for CY 2014. We are also finalizing a PFS procedure status indicator of I (Not valid for Medicare purposes. Medicare uses another code for the reporting of and the payment for these services) to CPT code 95941 for CY 2014, because for Medicare purposes, HCPCS code G0453 will continue to be used instead of CPT code 95941. Although we considered commenters' suggestions to value concurrent monitoring of up to 3 or 4 patients by a neurologist with the creation of additional G-codes for the remote monitoring of 2, 3 or 4 patients, creation of these G codes would allow billing for more than 60 minutes of work during a 60 minute time period. We continue to believe that HCPCS code G0453 adequately accounts for the relative resources involved when the physician monitors a Medicare beneficiary, while it

precludes inaccurate payment in cases where multiple patients are being monitored simultaneously. Therefore, we will maintain the current code descriptor for HCPCS code G0453.

<u>Comment</u>: Some commenters suggested we create mechanisms for practitioners to report the professional and technical components separately for CPT codes 95940 and HCPCS code G0453. One of these commenters suggested that creating separate technical component payment for the PFS would allow hospitals to approximate the relative resource costs associated with the technical component of the service.

Response: It is our understanding that these services are nearly always furnished to beneficiaries in facility settings. Therefore, Medicare would not make payments through the PFS that account for the clinical labor, disposable supplies, or medical equipment involved in furnishing the service. Instead, these resource costs would be included in the payment Medicare makes to the facility through other payment mechanisms. Therefore, we do not believe it would be appropriate to create separate payment rates for the professional and technical component of these services.

(40) Neurology System: Autonomic Function Tests (CPT code 95943)

As detailed in the CY 2013 final rule with comment period, we assigned a PFS procedure status of C to CPT code 95943, pursuant to the AMA RUC recommendation. (Contractors price the code. Contractors establish RVUs and payment amounts for these services.) The AMA RUC believes that a PFS procedure status of "C" was appropriate because they did not have sufficient information for making a specific work RVU recommendation.

<u>Comment</u>: Commenters opposed contractor pricing of CPT code 95943 because the other autonomic nervous system testing codes have national work RVUs and payment rates. Commenters suggested we crosswalk CPT code 95943 to CPT code 95924 due to the procedures' similarity in total work.

Response: We continue to believe that a PFS procedure status of C (Contractors price the code. Contractors establish RVUs and payment amounts for these services.) is appropriate for CPT code 95943.

We do not believe that the commenters provided sufficient data to value the service. Therefore, we are finalizing a Contractor Pricing procedure status to CPT code 95943 for CY 2014.

(41) Inpatient Neonatal Intensive Care Services and Pediatric and Neonatal Critical Care Services: Pediatric Critical Care Patient Transport (CPT codes 99485 and 99486)

For CY 2013, he CPT editorial panel created CPT codes 99485 and 99486, to describe the non-face-to-face services provided by physician to supervise interfacility care of critically ill or critically injured pediatric patients.

As detailed in the CY 2013 final rule with comment period, we reviewed CPT codes 99485 and 99486 and believed the services should be bundled into other services and not be separately payable. We believed the services were similar to CPT code 99288, which is also bundled on the PFS. The AMA RUC recommended a work RVU of 1.50 for CPT code 99485 and a work RVU of 1.30 for CPT code 99486. On an interim final basis for CY 2013, we assigned CPT codes 99485 and 99486 a PFS procedure status indicator of B (Payments for covered services are always bundled into payment for other services, which are not specified. If RVUs are shown, they are not used for Medicare payment. If these services are covered, payment for them is subsumed by the payment for the services to which they are bundled).

Comment: Commenters disagreed with our assignment of CPT codes 99485 and 99486 as bundled codes. They stated that that classification puts pediatric physicians at a disadvantage since the majority of non-Medicare payers will commonly bundle the codes as well. Commenters strongly recommended that we adopt status indicator A (Active) or, at the very least, status indicator N (Noncovered Service) for CPT codes 99485 and 99486.

Response: We continue to believe that CPT codes 99485 and 99486 are similar to CPT code 99288 and, like CPT code 99288, involve work that is already considered in the valuation of other services. Therefore, we do not believe that these services should be separately payable. Therefore, we are finalizing a PFS procedure status of B (Payments for covered services are always bundled into payment for other services, which are not specified. If RVUs are shown, they are not used for Medicare

payment. If these services are covered, payment for them is subsumed by the payment for the services to which they are bundled) to CPT codes 99485 and 99486 for CY 2014.

(42) Molecular Pathology (HCPCS code G0452)

As detailed in the CY 2013 final rule with comment period, one of the molecular pathology CPT codes that was deleted by CPT for CY 2012 was payable on the PFS: CPT code 83912-26. To replace this CPT code, we created HCPCS code G0452 to describe medically necessary interpretation and written report of a molecular pathology test, above and beyond the report of laboratory results. We reviewed the work associated with this procedure and we believed it was appropriate to directly crosswalk the work RVUs and times of CPT code 83912-26 to HCPCS code G0452, because we did not believe the coding change reflected a change in the service or in the resources involved in furnishing the service.

Accordingly, we assigned a work RVU of 0.37, with 5 minutes of preservice time, 10 minutes of intraservice time, and 5 minutes of postservice time to HCPCS code G0452 on an interim final basis for CY 2013.

<u>Comment</u>: Commenters disagreed with our valuation of HCPCS code G0452. Commenters expressed concern about the creation of a single HCPCS G-code to distinguish work related to a considerable number of procedures with changing relative values recommended by the AMA RUC.

Response: The decision to pay for molecular pathology codes under the CLFS required the creation of a new code for the interpretation and reporting services by pathologists on the PFS. We continue to believe that the creation of HCPCS code G0452 was appropriate to describe medically necessary interpretation and written report of a molecular pathology test, above and beyond the report of laboratory results. We also believe that this single HCPCS code is sufficient to capture the work involved in any of the numerous molecular pathology codes. Additionally, the professional component-only HCPCS G-code is a "clinical laboratory interpretation service," which is one of the current categories of PFS pathology services under the definition of physician pathology services at §415.130(b)(4). Therefore, we are finalizing a work RVU of 0.37 to HCPCS code G0452.

(43) Digestive System: Intestines (Except Rectum) (CPT code G0455)

For CY 2013, we created HCPCS code G0455 to be used for Medicare purposes instead of CPT code 44705. HCPCS code G0455 will be used to bundle the preparation and instillation of microbiota. CPT code 44705 was assigned a PFS procedure status indicator of I (Not valid for Medicare purposes).

After reviewing the preparation and instillation work associated with this procedure, we believed that CPT code 99213 was an appropriate crosswalk for the work and time of HCPCS code G0455. Therefore, on an interim final basis for CY 2013, we assigned a work RVU of 0.97 to HCPCS code G0455.

Commenters Commenters disagreed with our valuation of HCPCS code G0455.

Commenters opposed the interim final work RVU because they believed extensive work was required for the preparation of the microbiota, to determine if a patient was an appropriate candidate for fecal donation. Commenters believed that our work RVU valuation failed to distinguish between varying clinical circumstances for the use of this code. Commenters also suggested that we should consider coverage of more than one donor specimen screening when clinically suitable.

Response: After review, we agree with the commenters that the interim final work RVU of 0.97 undervalues this service. We believe that bundling the work RVU and physician time of CPT code 80500, a lab pathology consultation, with CPT code 99213 more appropriately values this work. Therefore, we are finalizing a work RVU of 1.34 and an intraservice time of 28 minutes for HCPCS code G0455.

- b. Finalizing CY 2013 Interim Direct PE Inputs
- (i) Background and Methodology

On an annual basis, the AMA RUC provides CMS with recommendations regarding direct PE inputs, including clinical labor, disposable supplies, and medical equipment, for new, revised, and potentially misvalued codes. We review the AMA RUC-recommended direct PE inputs on a code-by-code basis. When we determine that the AMA RUC recommendations appropriately estimate the direct PE inputs required for the typical service and reflect our payment policies, we use those direct PE inputs to value a service. If not, we refine the PE inputs to better reflect our estimate of the PE resources required for the service. We also confirm whether CPT codes should have facility and/or nonfacility direct PE inputs and refine the inputs accordingly.

In the CY 2013 PFS final rule with comment period (77 FR 69072), we addressed the general nature of some of our common refinements to the AMA RUC-recommended direct PE inputs as well as the reasons for refinements to particular inputs. In the following subsections, we respond to the comments we received regarding common refinements we made based on established principles or policies. Following those discussions, we summarize and respond to comments received regarding other refinements to particular codes.

We note that the interim final direct PE inputs for CY 2013 that are being finalized for CY 2014 are displayed in the final CY 2014 direct PE input database, available on the CMS website under the downloads for the CY 2014 PFS final rule at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html. The inputs displayed there have also been used in developing the CY 2014 PE RVUs as displayed in Addendum B of this final rule with comment period.

- (ii) Common Refinements
- (1) Equipment Time

Prior to CY 2010, the AMA RUC did not generally provide CMS with recommendations regarding equipment time inputs. In CY 2010, in the interest of ensuring the greatest possible degree of accuracy in allocating equipment minutes, we requested that the AMA RUC provide equipment times along with the other direct PE recommendations, and we provided the AMA RUC with general guidelines regarding appropriate equipment time inputs. We continue to appreciate the AMA RUC's willingness to provide us with these additional inputs as part of its direct PE recommendations.

In general, the equipment time inputs correspond to the service period portion of the clinical labor times. We have clarified this principle, indicating that we consider equipment time as the times within the intraservice period when a clinician is using the piece of equipment plus any additional time that the piece of equipment is not available for use for another patient due to its use during the designated procedure. For services in which we allocate cleaning time to portable equipment items, we do not include that time for the remaining equipment items as they are available for use for other patients during that time. In addition, when a piece of equipment is typically used during any additional visits included in a service's global period, the equipment time would also reflect that use.

We believe that certain highly technical pieces of equipment and equipment rooms are less likely to be used during all of the preservice or postservice tasks performed by clinical labor staff on the day of the procedure (the clinical labor service period) and are typically available for other patients even when one member of clinical staff may be occupied with a preservice or postservice task related to the procedure.

Some commenters have repeatedly objected to our rationale for refinement of equipment minutes on this basis. We acknowledge the comments we received that reiterate those objections

to this rationale and refer readers to our extensive discussion regarding those objections in the CY 2012 PFS final rule with comment period (76 FR 73182). In the following paragraphs we address new comments on this policy.

<u>Comment</u>: Several commenters pointed out that technician time is independent of physician time for some procedures so that equipment time should not be altered based on changes in physician intraservice time.

Response: The estimated time it takes for a practitioner or clinical staff to furnish a procedure is an important factor used in determining the appropriate direct PE input values used in developing nonfacility PE RVUs. For many services, the physician intraservice time serves as the basis for allocating the appropriate number of minutes within the service period to account for the time used in furnishing the service to the patient. In the case of many services, the number of physician intraservice minutes, or occasionally a particular proportion thereof, is allocated to both the clinical staff that assist the practitioner in furnishing the service and to the equipment used by either the practitioner or the staff in furnishing the service. This allocation reflects only the time the beneficiary receives treatment and does not include resources used immediately prior to or following the service. Additional minutes are often allocated to both clinical labor and equipment resources to account for the time used for necessary preparatory tasks immediately preceding the procedure or tasks typically performed immediately following it. For these services, we routinely adjust the minutes assigned to the direct PE inputs so that they correspond with the procedure time assumptions displayed in the physician time file that are used in determining work RVUs and allocating indirect PE values.

The commenters accurately point out that for a significant number of services, especially diagnostic tests, the procedure time assumptions used in determining direct PE inputs are

distinct from, and therefore not dependent on, physician intraservice time assumptions. For these services, we do not make refinements to the direct PE inputs based on changes to estimated physician intraservice times.

<u>Comment</u>: Several commenters asked that CMS identify what constitutes a highly technical piece of equipment.

Response: During our review of all recommended direct PE inputs, we consider whether or not particular equipment items would typically be used in the most efficient manner possible. In making this determination, we consider such items as the degree of specificity of a piece of equipment, which may influence whether the equipment item is likely to be stored in the same room in which the clinical staff greets and gowns, obtains vitals, or provides education to a patient prior to the procedure itself. We also consider the level of portability (including the level of difficulty involved in cleaning the equipment item) to determine whether an item could be easily transferred between rooms before or after a given procedure. We also examine the prices for the particular equipment items to determine whether the equipment is likely to be located in the same room used for all the tasks undertaken by clinical staff prior to and following the procedure. For each service, on a case-by-case basis, we look at the description provided in the AMA RUC recommendation and consider the overlap of the equipment item's level of specificity, portability, and cost; and, consistent with the review of other recommended direct PE inputs, make the determination of whether the recommended equipment items are highly technical.

(2) Standard Tasks and Minutes for Clinical Labor Tasks

In general, the preservice, service period, and postservice clinical labor minutes associated with clinical labor inputs in the direct PE input database reflect the sum of particular

tasks described in the information that accompanies the recommended direct PE inputs, "PE worksheets." For most of these described tasks, there are a standardized number of minutes, depending on the type of procedure, its typical setting, its global period, and the other procedures with which it is typically reported. At times, the AMA RUC recommends a number of minutes either greater than or less than the time typically allotted for certain tasks. In those cases, CMS clinical staff reviews the deviations from the standards to determine their clinical appropriateness. Where the AMA RUC-recommended exceptions are not accepted, we refine the interim final direct PE inputs to match the standard times for those tasks. In addition, in cases when a service is typically billed with an E/M, we remove the preservice clinical labor tasks so that the inputs are not duplicative and reflect the resource costs of furnishing the typical service.

In general, clinical labor tasks fall into one of the categories on the PE worksheets. In cases where tasks cannot be attributed to an existing category, the tasks are labeled "other clinical activity." In these instances, CMS clinical staff reviews these tasks to determine whether they are similar to tasks delineated for other services under the PFS. For those tasks that do not meet this criterion, we do not accept those clinical labor tasks as direct inputs.

<u>Comment</u>: Several commenters objected to CMS's refinement to recommended clinical labor minutes to meet these standards in cases where the recommendation included information suggesting that the service requires specialized clinical labor tasks, especially relating to quality assurance documentation, that are not typically included on the PE worksheets.

Response: Although we appreciate the importance of quality assurance and other tasks, we note that the nonfacility direct PE inputs include an estimated number of clinical labor minutes for most codes developed based on an extensive, standard list of clinical labor tasks such as "prepare equipment," and "prepare and position patient." We believe that quality assurance

documentation tasks for services across the PFS are already accounted for in the overall estimate of clinical labor time. We do not believe that it would serve the relativity of the direct PE input database were additional minutes added for each clinical task that could be discretely described for every code and thus are not making any changes based upon this comment.

(3) Equipment Minutes for Film Equipment Inputs

In general, the equipment time allocated to film equipment, such as "film processor, dry, laser" (ED024), "film processor, wet" (ED025), and "film alternator (motorized film viewbox)" (ER029), corresponds to the clinical labor task "hang and process film."

<u>Comment</u>: Several commenters argued that the film equipment should be allocated for the entire service period.

Response: We believe that the film equipment, when used, is typically only used during the time associated with certain clinical labor tasks, and is otherwise generally available for use in furnishing services to other patients. In reviewing these equipment inputs in the direct PE input database, we note that this equipment is generally not allocated for the full number of minutes of the clinical labor service period. Because we do not believe that this equipment would be in use during periods other than during particular clinical labor tasks, and to maintain relativity, we are finalizing the CY 2013 direct PE inputs based on this general principle.

(4) Film Inputs as a Proxy for Digital Imaging Inputs

<u>Comment</u>: A few commenters objected to our refinement of certain film inputs including eliminating VHS video system and tapes, and reducing the number of films for several procedures.

Commenters also stated that the film processor was a necessary input for several procedures from which it was removed.

Response: As stated in the CY 2013 PFS final rule with comment period (77 FR 69029), a variety of imaging services across the PFS include direct PE inputs that reflect film-based technology instead of digital technology. We believe that for imaging services, digital technology is more typical

than film technology. However, stakeholders, including the AMA RUC, have recommended that we continue to use film technology inputs as a proxy for digital until digital inputs for all imaging services can be considered. In response to these recommendations, we have maintained inputs for film-based technology as proxy inputs while this review occurs. In the case of new, revised, and potentially misvalued codes, we have accepted the recommended proxy inputs to the extent that the recommended proxy inputs are those that are usually associated with imaging codes. However, we have not accepted recommended inputs that are not usually included in other imaging services. We have reviewed the recommended inclusion of the film processor and, upon additional review, noted that the item is routinely included in other imaging codes. Therefore, we are including that item in the direct PE input database. We anticipate updating all of the associated inputs in future rulemaking. After consideration of comments received, we are finalizing the direct PE inputs in accordance with this general principle with the additional refinement of inserting the film processor for relevant codes.

(iii) Code-Specific Direct PE Inputs

We note that we received many comments objecting to refinements made based on CMS clinical review (including our determination that certain recommended items were duplicative of others already included with the service), statutory requirements, or established principles and policies under the PFS. We note that for many of our refinements, the medical specialty societies that represent the practitioners who furnish the service objected to most of these refinements for the general reasons described above or for the reasons we respond to in the "background and methodology" portion of this section. Below, we respond to comments in which commenters address specific CPT/HCPCS codes and provide rationale for their objections to our refinements in the form of new information supporting the inclusion of the items and/or times requested. When discussing these refinements, rather than listing all refinements made for each service, we discuss only the specific refinements that meet these criteria. We indicate the presence of other refinements by noting "among other refinements" after delineating the specific refinements for a particular service or group of services. For those comments that stated that an item was "necessary for the service" and no additional rationale or evidence was provided, we conducted further review to

determine whether the inputs as refined were appropriate and concluded that the inputs as refined were indeed appropriate.

Further, in the CY 2013 PFS correction notice (78 FR 48996), we addressed several technical and typographical errors that respond to comments received. We do not repeat those comments nor provide our responses for those items here.

(1) Cross-Family Comments

<u>Comment</u>: We received comments regarding refinements to equipment times for many procedures, in which commenters indicated that the equipment time for the procedure should include the time that the equipment is unavailable for other patients, including while preparing equipment, positioning the patient, assisting the physician, and cleaning the room.

Response: As stated above, we agree with commenters that the equipment time should include the times within the intraservice period when a clinician is using the piece of equipment plus any additional time the piece of equipment is not available for use for another patient due to its use during the designated procedure. We believe that some of these commenters are suggesting that we should allocate the full number of clinical labor minutes included in the service period to the equipment items. However, as we have explained, the clinical labor service period includes minutes based on some clinical labor tasks associated with preservice and postservice activities that we do not believe typically preclude equipment items from being used in furnishing services to other patients because these activities typically occur in other rooms.

The equipment times allocated to the CPT codes in Table 25 already include the full intraservice time the equipment is typically used in furnishing the service, plus additional minutes to reflect time that the equipment is unavailable for use in furnishing services to other patients.

TABLE 25: Equipment Inputs that Include Appropriate Clinical Labor Tasks
About Which Comments Were Received

CPT	Equipment
Code	Items
50590	EQ175

CPT	Equipment		
Code	Items		
52214	all items		
52224	all items		
72040	EL012		
72050	EL012		
72052	EL012		
72192	EL007		
72193	EL007		
72194	EL007		
73221	EL008		
73721	EL008		
74150	EL007		
74160	EL007		
74170	EL007		
74175	EL007		
74177	EL007		
74178	EL007		
77301	ER005		
78012	ER063		
78013	ER032		
78014	EF010, ER063		
78070	ER032		
78071	ER032		
93925	EL016		
93926	EL016		
93970	EL016		

Comment: Some commenters stated that selected items added to various CPT codes during clinical review by CMS were not typical. In Table 26, we list those services and items identified by commenters as atypical for the service. For each of these items, we note whether we maintained our refinement or removed the input based on commenter recommendation. In general, we have accepted the comments to remove the items, except when we believed that doing so would deviate from our standard policies. Specifically, as we discuss above, we are maintaining standard times for clinical labor tasks; these include 10 minutes for "clean surgical instrument package" for CPT codes 11301 – 11313, the time

for "Assist physician in performing procedure" to conform to physician time for CPT code 13150, and the equipment minutes used exclusively for the patient for "lane, screening (oph)" (EL006) for CPT codes 92081, 92082, and 92083.

TABLE 26: Items Identified As Not Typical By Commenters

CPT Code/ Code Range	CMS Code	CMS Code Description	Labor Activity (If Applicable)	AMA RUC Recommend- ation	CMS Refinement	Commenter Recommend- ation	CMS Decision/ Rationale
11301- 11313	L037D	RN/LPN/MTA	Clean Surgical Instrument Package	1	10	1	Maintain refinement/ Standard Time
13150	L037D	RN/LPN/MTA	Assist physician in performing procedure	20	26	20	Maintain refinement/ Standard Time
	SA067	tray, shave prep		0	1	0	Removed
32554	SB001	cap, surgical		0	2	0	Removed
32334	SB039	shoe covers, surgical		0	2	0	Removed
	SA044	pack, moderate sedation		0	1	0	Removed
	SA067	tray, shave prep		0	1	0	Removed
	SB001	cap, surgical		0	2	0	Removed
32556	SB039	shoe covers, surgical		0	2	0	Removed
	SC010	closed flush system, angiography		0	1	0	Removed
	SH065	sodium chloride 0.9% flush syringe		0	1	0	Removed
	SH069	sodium chloride 0.9% irrigation (500-1000ml uou)		0	1	0	Removed
32557	SB027	gown, staff, impervious		0	1	0	Removed
	SG078	tape, surgical occlusive 1in		0	25	0	Removed

CPT Code/ Code Range	CMS Code	CMS Code Description	Labor Activity (If Applicable)	AMA RUC Recommend- ation	CMS Refinement	Commenter Recommend- ation	CMS Decision/ Rationale
		(Blenderm)					
67810	SB011	drape, sterile, fenestrated 16in x 29in		0	1	0	Removed
72192	SK076	slide sleeve (photo slides)		0	1	0	Removed
/2192	SK098	film, x-ray, laser print		0	8	4	Removed
72193	SH065	sodium chloride 0.9% flush syringe		0	15	1	Removed
	SK076	slide sleeve (photo slides)		0	1	0	Removed
74150	SK076	slide sleeve (photo slides)		0	1	0	Removed
74130	SK098	film, x-ray, laser print		0	8	4	Removed
74160	SH065	sodium chloride 0.9% flush syringe		0	15	1	Removed
74170	SH065	sodium chloride 0.9% flush syringe		0	15	1	Removed
92081	EL006	lane, screening (oph)		12	17	12	Maintain refinement/ Standard Time
92082	EL006	lane, screening (oph)		22	27	22	Maintain refinement/ Standard Time
92083	EL006	lane, screening (oph)		32	37	32	Maintain refinement/ Standard Time
93017	L051A	RN	Complete diagnostic forms, lab & X-ray	0	4	0	Removed

CPT Code/ Code Range	CMS Code	CMS Code Description	Labor Activity (If Applicable)	AMA RUC Recommend- ation	CMS Refinement	Commenter Recommend- ation	CMS Decision/ Rationale
			requisitions				

(2) Integumentary system: Skin, Subcutaneous, and Accessory Structures (CPT codes 11300, 11301, 11302, 11303, 11305, 11306, 11307, 11308, 11310, 11311, 11312, 11313)

In establishing interim final direct PE inputs for CY 2013, CMS refined the AMA RUC's recommendation for CPT codes 11300 (Shaving of epidermal or dermal lesion, single lesion, trunk, arms or legs; lesion diameter 0.5 cm or less), 11301 (Shaving of epidermal or dermal lesion, single lesion, trunk, arms or legs; lesion diameter 0.6 to 1.0 cm), 11302 (Shaving of epidermal or dermal lesion, single lesion, trunk, arms or legs; lesion diameter 1.1 to 2.0 cm), 11303 (Shaving of epidermal or dermal lesion, single lesion, trunk, arms or legs; lesion diameter over 2.0 cm), 11305 (Shaving of epidermal or dermal lesion, single lesion, scalp, neck, hands, feet, genitalia; lesion diameter 0.5 cm or less), 11306 (Shaving of epidermal or dermal lesion, single lesion, scalp, neck, hands, feet, genitalia; lesion diameter 0.6 to 1.0 cm), 11307 (Shaving of epidermal or dermal lesion, single lesion, scalp, neck, hands, feet, genitalia; lesion diameter 1.1 to 2.0 cm), 11308 (Shaving of epidermal or dermal lesion, single lesion, scalp, neck, hands, feet, genitalia; lesion diameter over 2.0 cm), 11310 (Shaving of epidermal or dermal lesion, single lesion, face, ears, evelids, nose, lips, mucous membrane; lesion diameter 0.5 cm or less), 11311 (Shaving of epidermal or dermal lesion, single lesion, face, ears, eyelids, nose, lips, mucous membrane; lesion diameter 0.6 to 1.0 cm), 11312 (Shaving of epidermal or dermal lesion, single lesion, face, ears, eyelids, nose, lips, mucous membrane; lesion diameter 1.1 to 2.0 cm), and 11313 (Shaving of epidermal or dermal lesion, single lesion, face, ears, eyelids, nose, lips, mucous membrane; lesion diameter over 2.0 cm) by removing "electrocautery-hyfrecator, up to 45 watts" (EQ110), and "cover, probe (cryosurgery)" (SB003), among other refinements.

<u>Comment</u>: Commenters noted that there is an "inherent and persistent risk of bleeding" during these procedures, and that the electrocautery-hyfrecator needs to be readily available to prevent excessive

blood loss and is typically included in the surgical field. These commenters explained that the item, "cover, probe (cryosurgery)" is the generic sterile sheath that covers the electrocautery-hyfrecator penhandle and cable, and therefore required to be used with the electrocautery-hyfrecator.

Response: In our clinical review, we reviewed the work vignettes for these procedures, which did not include the use of the electrocautery-hyfrecator as a part of the procedure. Although we acknowledge that the electrocautery-hyfrecator needs to be readily available during the procedure, we note that "standby" equipment, or items that are not used in the typical case, are considered indirect costs. For further discussion of this issue, we refer readers to our discussion of "standby" equipment in the CY 2001 PFS proposed rule (65 FR 44187). With regard to the "cover, probe (cryosurgery)", this item is a disposable supply that would only be used with each patient if the electrocautery-hyfrecator is in the sterile field during all procedures. We do not have information to suggest that the electrocautery-hyfrecator is typically in the sterile field, so we are not including the supply item "cover, probe (cryosurgery)" in the direct PE database for this service. After consideration of the comments received, we are finalizing the CY 2013 interim final direct PE inputs for 11300-11313 as established.

(3) Integumentary System: Repair (Closure) (CPT Codes 13100, 13101, 13102, 13120, 13121, 13122, 13131, 13132, 13133, 13152, and 13153)

In establishing interim final direct PE inputs for CY 2013, CMS refined the AMA RUC's recommendations for CPT codes 13100 (Repair, complex, trunk; 1.1 cm to 2.5 cm), 13101 (Repair, complex, trunk; 2.6 cm to 7.5 cm), 13102 (Repair, complex, trunk; each additional 5 cm or less (list separately in addition to code for primary procedure)), 13120 (Repair, complex, scalp, arms, and/or legs; 1.1 cm to 2.5 cm), 13121 (Repair, complex, scalp, arms, and/or legs; 2.6 cm to 7.5 cm), 13122 (Repair, complex, scalp, arms, and/or legs; each additional 5 cm or less (list separately in addition to code for primary procedure)), 13131 (Repair, complex, forehead, cheeks, chin, mouth, neck, axillae, genitalia, hands and/or feet; 1.1 cm to 2.5 cm), 13132 (Repair, complex, forehead, cheeks, chin, mouth, neck, axillae, genitalia, hands and/or feet; 2.6 cm to 7.5 cm), 13133 (Repair, complex, forehead, cheeks, chin, mouth, neck, axillae, genitalia, hands and/or feet; each additional 5 cm or less (list separately in addition

to code for primary procedure)), 13150 (Repair, complex, eyelids, nose, ears and/or lips; 1.0 cm or less), 13151 (Repair, complex, eyelids, nose, ears and/or lips; 1.1 cm to 2.5 cm), 13152 (Repair, complex, eyelids, nose, ears and/or lips; 2.6 cm to 7.5 cm), and 13153 (Repair, complex, eyelids, nose, ears and/or lips; each additional 5 cm or less (list separately in addition to code for primary procedure)) by removing duplicative items, among other refinements.

Comment: A few commenters argued that the majority of procedures reported using CPT codes 13100, 13101, 13120, 13121, 13131, 13132, 13150, 13151, and 13153 are furnished under local anesthesia, delivered by subcutaneous injection, and therefore typically require "needle, 18-27g" (SC029). Commenters also pointed out that the second "gown, staff, impervious" (SB027) and "mask, surgical" (SB033) are not duplicative, but required, because an assistant at surgery is allowed for these surgeries in some cases, and OSHA requirements mandate that health care workers be protected from blood exposure. Commenters stated that they did not believe these procedures could be furnished without these inputs.

Response: Based on the rationale provided by commenters, we agree that the needle should be included as a direct PE input for this family of codes. However, we continue to believe that a second gown and mask are not typical because our claims data show that an assistant at surgery is rarely, if ever, used for these services.

After consideration of the comments received, we are finalizing the CY 2013 interim final direct PE inputs for 13100 – 13153 with the additional refinement of incorporating the "needle, 18-27g" (SC029) as recommended by commenters.

(4) Integumentary System: Nails (CPT Code 11719)

In establishing interim final direct PE inputs for CY 2013, we refined the AMA RUC recommendation for CPT code 11719 by adjusting the times allocated for clinical labor tasks as follows: "Provide preservice education/obtain consent" from 2 minutes to 1 minute, "Greet patient, provide gowning, assure appropriate medical records are available" from 3 minutes to 1 minute, "Prepare room,

equipment, supplies" from 2 minutes to 1 minute, and "Clean room/equipment by physician staff" from 3 minutes to 1 minute, among other refinements.

<u>Comment</u>: A commenter objected to our refinements to this clinical labor task, and argued that one minute of "provide preservice education/obtain consent" is inadequate to review the advanced beneficiary notice (ABN) and answer patient questions. This commenter also objected to our decreasing the number of minutes associated with the other clinical labor activities to below the AMA-RUC recommended standard minutes.

Response: We believe that the time assigned to "provide preservice education/obtain consent" appropriately reflects the resources required in furnishing the typical procedure and thus are not making the change requested, particularly since five minutes of preservice physician time are also included for the service. We also would not expect an ABN to be provided in the typical case. We agree with commenters that we should allocate the standard number of minutes for the remaining clinical labor activities and have adjusted the direct PE database accordingly.

<u>Comment</u>: One commenter suggested that it was typical to position a patient in a power table/chair in lieu of an exam table when furnishing this service.

Response: CMS clinical staff reviewed CPT code 11719 in the context of this comment. We do not believe that it is typical that a power table/chair would be used for these procedures. After considering the comments received, we are finalizing the CY 2013 interim final direct PE inputs for CPT code 11719 as established, with the exception of increasing the minutes assigned to clinical labor activities to the standard number of minutes.

(5) Arthrocentesis (CPT Codes 20600, 20605, 20610).

In establishing direct PE inputs for CY 2013, we refined the AMA RUC's recommendations for CPT codes 20600 (Arthrocentesis, aspiration and/or injection; small joint or bursa (eg, fingers, toes), 20605 (Arthrocentesis, aspiration and/or injection; intermediate joint or bursa (eg, temporomandibular, acromioclavicular, wrist, elbow or ankle, olecranon bursa)), and 20610 (Arthrocentesis, aspiration and/or injection; major joint or bursa (eg, shoulder, hip, knee joint, subacromial bursa)) by removing the minutes

associated with the clinical labor activity "discharge day management" and replacing these minutes with "conduct phone calls/call in prescriptions" in the facility setting.

<u>Comment</u>: Commenters requested clarification as to whether the time allocated for "conduct phone calls/call in prescriptions" is limited to the facility setting or is also included in the non-facility setting.

Response: The AMA RUC recommendation included "conduct phone calls/call in prescriptions" in the nonfacility setting and we did not refine this recommendation. Therefore, this activity is included in the inputs for the nonfacility setting as well.

<u>Comment</u>: One commenter suggested it was typical for a physician to position a patient in a power table/chair in lieu of an exam table when furnishing 20600 and 20605.

Response: Our clinical staff reviewed CPT codes 20600 and 20605 in the context of this comment. We do not believe that it is typical that a power table/chair would be used for these procedures. After considering the comments received, we are finalizing the CY 2013 interim final direct PE inputs for CPT codes 20600, 20605, and 20610 as established.

(6) Respiratory System: Accessory Sinuses (CPT Code 31231)

In establishing interim final direct PE inputs for CY 2013, we refined the AMA RUC's recommendation for CPT code 31231 (Nasal endoscopy, diagnostic, unilateral or bilateral (separate procedure)) by removing the second "endoscope, rigid, sinoscopy" (ES013) from the inputs for the service, refining the equipment time to reflect typical use exclusive to the patient, and removing the time allocated to preservice clinical labor tasks, among other refinements.

<u>Comment</u>: A commenter disagreed with our removal of the second endoscope, arguing that the second scope is medically necessary because the first scope (zero degree rigid scope) does not allow visualizing above or behind all the normal structures of the nasal vault such as superior turbinate and the frontal recess. The second scope (for example, a 30, 45 or 70 degree scope) is used more than 51 percent of the time.

Response: We agree with the commenter that the second scope is used in the typical case, and based on this comment; we are adding the second scope to the direct PE inputs for the service.

<u>Comment</u>: A commenter disagreed with our refinements to the equipment time for this service, and stated that the entire clinical labor service period time of 63 minutes, and at a minimum, 43 minutes, should be allocated to all equipment used in this procedure.

Response: In general, for equipment that we do not consider to be highly technical, we allocate the entire service period time, with the exception of the time allocated for cleaning of other, portable pieces of equipment. Therefore, we agree with the commenter that the equipment times should be modified, but do not agree with the commenter that 63 minutes should be allocated. Instead, we are modifying the time allocated for the equipment in this procedure by assigning 53 minutes to the instrument pack to reflect the intraservice time other than cleaning of the scopes, 48 minutes to the scopes to reflect the intraservice time other than the cleaning of the instrument pack, and 38 minutes to the remaining equipment items, which reflects the entire intraservice clinical labor time except for the time allocated for cleaning the portable equipment items instrument pack and scope.

<u>Comment</u>: Commenters argued that the preservice clinical labor tasks included in the RUC recommendation should have been maintained in this procedure.

Response: This procedure is typically billed with an E/M service, and the preservice tasks are already included as direct PE inputs for the E/M services. Therefore, we believe that including these items again in CPT 31231 would be duplicative.

After consideration of public comments, we are finalizing the CY 2013 interim final direct PE inputs for 31231 as established with the additional refinements of adding in the second scope as an equipment item and adjusting the equipment times as discussed above.

(7) Respiratory System: Lungs and Pleura (CPT Codes 32554, 32555, and 32557)

In establishing interim final direct PE inputs for CY 2013, we refined the AMA RUC's recommendation for CPT codes 32554 (Removal of fluid from chest cavity), 32555 (Removal of fluid from chest cavity with imaging guidance), and 32557 (Removal of fluid from chest cavity with insertion

of indwelling catheter and imaging guidance), by inserting supply item "kit, pleural catheter insertion" (SA077) and refining the equipment times to reflect the typical use exclusive to the patient.

Comment: Commenters indicated that a tunneled catheter is not used during this procedure, so that the pleural catheter insertion kit is not an accurate supply item to use as the thoracentesis kit (SA113). The commenter also pointed out that the price of the thoracentesis kit that appears in the direct PE input database appeared to be inaccurately priced at \$260.59. The commenter pointed out that the price listed in the database reflects an invoice that includes ten units, so that the accurate price for the items is \$26.06.

Response: Based on the information provided by commenters, we agree that supply item "Kit, thoracentesis" (SA113) would be more appropriate than "kit, pleural catheter insertion" (SA077) and we agree that the correct price for the item is \$26.06. We have updated this price in the direct PE input database accordingly.

<u>Comment</u>: Commenters stated that the time allocated to equipment items "room, ultrasound, general" (EL015) and "room, CT" (EL007), as well as "light, exam" (EQ168) should reflect the time for tasks during which the room is not available to other patients; specifically, for CPT code 32555, 33 minutes should be assigned to EL015, and for CPT code 32557, 45 minutes should be assigned to EL007 and EQ168.

Response: We agree with commenters that it is consistent with our stated policy to allocate time for highly technical equipment for preparing the room, positioning the patient, acquiring images, and cleaning the room. Therefore, for CPT code 32555, we are assigning 33 minutes to "room, ultrasound, general" (EL015), and for CPT code 32557, we are assigning 45 minutes to "room, CT" (EL007) and "light, exam" (EQ168).

After reviewing the public comments received, we are finalizing the CY 2013 interim final direct PE inputs for CPT codes 32554, 32555, and 32557 as established with the additional refinements of including and updating the price of the "kit, thoracentesis" (SA113) supply item and adjusting the equipment times as commenters recommended.

(8) Cardiovascular System: Heart and Pericardium (CPT codes 33361, 33362, 33363, 33364, 33365, and 33405)

In establishing interim final direct PE inputs for CY 2013, we refined the AMA RUC's recommendation for CPT codes 33361, 33362, 33363, 33364, and 33365 by refining the time allocated to clinical labor tasks in the preservice and postservice periods to be consistent with the standards for adjusted 000-day global services.

<u>Comment</u>: Commenters stated that these services are furnished in a facility setting, requiring a fully equipped operating room or hybrid suite. The commenter detailed the various clinical labor tasks that are needed for these procedures, and noted that the requirements are similar to those of 90-day global procedures.

Response: We agree with commenters that it would be appropriate to allocate the standard 90-day global clinical labor inputs for these services. After consideration of public comments, we are finalizing the CY 2013 interim final direct PE inputs for CPT codes 33361-33365 as established, with the additional refinement of replacing the current times for clinical labor tasks with those of the standard 90-day global inputs.

We also refined the direct PE inputs for CPT code 33405 by removing the clinical labor activity, "Additional coordination between multiple specialties for complex procedures (tests, meds, scheduling, etc.) prior to patient arrival at site of service."

<u>Comment</u>: A commenter stated that inclusion of the time allocated for this additional coordination activity is consistent with other major surgical procedures, and that removing it would create an anomaly with other cardiac procedures.

Response: We do not agree that it is appropriate to include these "additional coordination" tasks as inputs to this procedure. We thank the commenter for bringing to our attention the potential anomaly created by having this activity included in other procedures and will consider any relativity issues regarding clinical labor preservice minutes allocated for other procedures in future rulemaking. After

consideration of the comments received, we are finalizing the CY 2013 direct PE inputs for CPT code 33405 as established.

(9) Cardiovascular System: Arteries and Veins (CPT codes 36221, 36222, 36223, 36224, 36225, 36226, 36227, 36228, and 37197)

In establishing interim final direct PE inputs for CY 2013, we refined the AMA RUC's recommendation for CPT codes 36221 (Insertion of catheter into chest aorta for diagnosis or treatment), 36222 (Insertion of catheter into neck artery for diagnosis or treatment), 36223 (Insertion of catheter into neck artery for diagnosis or treatment), 36225 (Insertion of catheter into chest artery for diagnosis or treatment), 36226 (Insertion of catheter into chest artery for diagnosis or treatment), 36226 (Insertion of catheter into chest artery for diagnosis or treatment), and 36227 (Insertion of catheter into neck artery for diagnosis or treatment) by substituting equipment item "table, instrument, mobile" (EF027) for equipment item "Stretcher" (EF018), refining equipment time to reflect typical use exclusive to the patient for equipment items "room, angiography" (EL011), "contrast media warmer" (EQ088), and "film alternator (motorized film viewbox)" (ER029), and removing the recommended minutes based on the clinical labor task described as "image post processing" from CPT code 36221, among other refinements.

<u>Comment</u>: Commenters stated that they believed that the removal of the stretcher was an error because a stretcher is necessary for these cerebral angiography codes and requested that the stretcher be included as an input for these procedures.

Response: We do not agree with commenters that it is appropriate to include a stretcher for this family of codes. The inclusion of a stretcher is not consistent with the AMA RUC-recommended standardized nonfacility direct PE inputs that account for moderate sedation as typically furnished as a part of such service, which we used as the basis for proposing and finalizing a standard package of direct PE inputs for moderate sedation during CY 2012 rulemaking. For further discussion of this issue, we refer readers to the CY 2012 PFS rule (76 FR 73044).

<u>Comment</u>: Commenters stated the CMS refinement for equipment minutes was inappropriate, and that the equipment time for "room, angiography" (EL011), "contrast media warmer" (EQ088), and

"film alternator (motorized film viewbox)" (ER029) should include the clinical labor tasks of "prepare room," "prepare and position patient," "sedate patient," "assist physician/acquire images," and "clean room." Specifically, commenters requested that we adjust the time for all equipment items as follows: 49 minutes for CPT code 36221, 59 minutes for CPT code 36222, 64 minutes for CPT code 36223, 69 minutes for CPT code 36224, 64 minutes for CPT code 36225, and 69 minutes for CPT code 36226.

Response: We agree with commenters that the time allocated to the equipment should account for these tasks. We are adjusting the equipment times for "room, angiography" (EL011), "contrast media warmer" (EQ088), and "film alternator (motorized film viewbox)" (ER029) to those identified by the commenters and described above.

<u>Comment</u>: A commenter noted that "image post processing" often appears as a clinical labor task activity on the PE worksheet and that the task is integral to patient care for the services described by these codes. Commenters requested that we include these clinical labor tasks for these procedures.

Response: Upon further review of similar codes, we agree with the commenter that it is consistent with other services in this family to include clinical labor minutes based on the "image post processing" task. After consideration of public comments, we are finalizing the CY 2013 interim final direct PE inputs for CPT codes 36221 - 36227 as established with the additional refinements of the adjusted equipment and clinical labor times noted above.

We also refined the AMA RUC's recommendation for direct PE inputs for CPT code 36228 (Insertion of catheter into neck artery for diagnosis or treatment) by removing 1 minute of clinical labor time, based on the task called "prepare room, equipment, and supplies," and 1 minute for "assisting with fluoroscopy/image acquisition." We also refined the recommendation by not including the supply item "syringe, 5-6 ml" (SC075).

<u>Comment</u>: Commenters stated that the additional minute for "prepare room, equipment, and supplies" is necessary for this add-on code. They also requested that we adjust the time for acquiring images as well. Commenters also stated that the syringe is necessary to safely inject micro-catheters and should be included.

Response: We do not agree with commenters that an additional minute should be added to the clinical labor time for this add-on code to account for additional time to "prepare the room, equipment, and supplies." As we stated in the CY 2013 PFS final rule with comment period (77 FR 68933), we believe that preparing the room would not typically be duplicated when furnishing a subsequent procedure to the same patient on the same day, and we believe that the standard number of minutes allocated on the basis of the clinical labor task accounts for the typical amount time spent preparing the items for the primary procedure, regardless of whether or not a separate code is reported for some cases. However, based on the commenters' explanation, we agree that an additional minute for image acquisition is typical when the add-on code is reported. We also agree that the syringe is necessary for this procedure.

After reviewing public comments received, we are finalizing the CY 2013 direct PE inputs for CPT code 36228 as established with the additional refinements to the clinical labor and supply items noted above.

In establishing interim final direct PE inputs for CY 2013, we refined the AMA RUC's recommendation for CPT code 37197 (Retrieval of intravascular foreign body) by removing equipment items "ultrasound unit, portable" (EQ250) and "contrast media warmer" (EQ088), and supply items "sheath-cover, sterile, 96in x 6in (transducer)" (SB048), "catheter, (Glide)" (SD147), "guidewire, Amplatz wire 260 cm" (SD252), and "sodium chloride 0.9% flush syringe" (SH065).

<u>Comment</u>: Commenters indicated that the portable ultrasound unit is necessary to gain vascular access, the contrast media warmer is necessary for the procedure, and the supply items we refined from the AMA RUC recommendation are also required for the procedures since the foreign body cannot be removed without these items.

Response: We do not agree that the portable ultrasound unit should be included as a direct PE input for this procedure. The CPT description of this code states that either fluoroscopy or ultrasound is used; the angiography room accounts for the resources associated with fluoroscopy. When fluoroscopy is used, these resources are appropriately accounted for. In the event that a portable ultrasound unit is used

in place of fluoroscopy, the resource costs would be significantly overestimated, since a portable ultrasound unit is far less expensive than the angiography room. Therefore, we continue to believe that the PE inputs adequately account for the resource costs used for imaging in this procedure. We also continue to believe that the supply items we refined from the AMA RUC recommendation are duplicative since the inputs for this service already include supply items that are used for removing the foreign body during the procedure. We agree with commenters that the contrast media warmer should be included in the procedure, and are including this equipment item as a direct PE input for this service.

After consideration of these comments, we are finalizing the CY 2013 interim final direct PE inputs for CPT code 37197 as established with the additional refinement of adding the equipment item "contrast media warmer" (EQ088), as noted above.

(10) Digestive System: Intestines (Except Rectum) (CPT code 44705 and HCPCS code G0455)

In establishing interim final direct PE inputs for CY 2013, CMS crosswalked the inputs from 44705 (Prepare fecal microbiota for instillation, including assessment of donor specimen) to G0455 (Preparation with instillation of fecal microbiota by any method, including assessment of donor specimen), and incorporated a minimum multi-specialty visit pack (SA048) and an additional 17 minutes of clinical labor time in the service period based on the amount of time allocated for clinical labor tasks in the direct PE inputs for E/M services. In the CY 2013 final rule with comment period, we noted that Medicare would only pay for the preparation of the donor specimen if the specimen is ultimately used for the treatment of a beneficiary. Accordingly, we bundled preparation and instillation into a HCPCS code, G0455, to be used for Medicare beneficiaries instead of the new CPT code 44705 (Preparation of fecal microbiota for instillation, including assessment of donor specimen), which we assigned a PFS procedure status indicator of I (Not valid for Medicare purposes). G0455 includes both the work of preparation and instillation of the microbiota.

<u>Comment</u>: A commenter asserted that CMS listed G0455 as having a PE RVU of 2.48 without explaining how this value was derived.

Response: In the CY 2013 PFS final rule with comment period (77 FR 69073), we described how we established the direct PE inputs for G0455. Specifically, we stated that we used the AMA RUC-recommended nonfacility PE inputs for CPT code 44705, in addition to 17 minutes of clinical labor time and a "minimum multi-specialty visit pack" (SA048), to account for both the preparation and instillation. The PE RVU of 2.48 results from the standard methodology outlined in PFS rules in the section entitled "Resource-Based Practice Expense (PE) Relative Value Units (RVUs)" (see, for example, 77 FR 68899). After consideration of the public comment, we are finalizing the interim final direct PE inputs for HCPCS code G0455 as established.

(11) Digestive System: Biliary Tract (CPT Codes 47600 and 47605)

In establishing interim final direct PE inputs for CY 2013, we refined the AMA RUC's recommendation for CPT codes 47600 (Removal of gallbladder) and 47605 (Removal of gallbladder with X-ray study of bile ducts) by replacing the supply item "pack, post-op incision care (suture & staple)" (SA053) with supply item "pack, post-op incision care (suture)" (SA054).

<u>Comment</u>: Commenters stated that although sutures and staples are sometimes both used, at a minimum, staples are used in this procedure. Therefore, commenters requested that, as a minimum, we include the staple removal pack.

Response: We agree with the commenters that the staple removal pack (SA052) should be included instead of the suture pack. After consideration of these comments, we are finalizing the CY 2013 interim final direct PE inputs for CPT codes 47600 and 47605 as established, with the additional refinement of substituting the staple removal pack (SA052) for the suture removal pack (SA054).

(12) Urinary System: Bladder (CPT Codes 52214, 52224, and 52287)

In establishing the interim final direct practice expense inputs for CY 2013 for CPT code 52214, we refined the AMA RUC recommendation to remove supply items "drape-towel, sterile, 18in x 26in" (SB019), "lidocaine 1%-2% inj (Xylocaine)" (SH047), and "penis clamp."

<u>Comment</u>: Commenters indicated that the supply item "drape-towel, sterile, 18in x 26in," is used on the instrument table and that the supply item "lidocaine 1%-2% inj (Xylocaine)" (SH047), is used to

instill into the bladder as a numbing agent. Commenters also indicated that the item "penis clamp" is required to keep the lidocaine in the penile urethra.

Response: We agree with commenters that the drape towel and lidocaine should be included in this procedure. However, we do not agree that the reusable penis clamp, even when typically used, should be included in the direct PE input database for this procedure. Since the item is reusable, the resource cost associated with the item is not considered to be a direct PE supply input. Given the price associated with the item, the cost per minute over several years of useful life becomes negligible relative to the other costs accounted for in the PE methodology. We refer readers to a discussion of equipment items under \$500 in the NPRM for CY 2005 (69 FR 47494). We note that including such items as equipment in the direct PE input database would not impact the PE RVU values.

In establishing the interim final direct practice expense inputs for CY 2013, we refined the AMA RUC recommendation for CPT code 52224 by adjusting the equipment time for "fiberscope, flexible, cystoscopy" (ES018) to 94 minutes, adjusting the clinical labor activity "prepare biopsy specimen" to 2 minutes, and adjusting the quantity of the supply item "gloves, sterile" (SB024) to 1 pair, and "cup, biopsy-specimen sterile 4oz" (SL036) to 3, among other refinements.

<u>Comment</u>: Commenters stated that the time for this equipment item should include all standard tasks, in addition to the cleaning of the scope. Commenters also noted that, depending upon the number of biopsies, the preparation of the specimen can take more than 2 minutes, that a minimum of 3 pairs of gloves are required, and that biopsy specimens are submitted in several containers.

Response: We re-examined the time for the fiberscope and agree with commenters that the time should include all time associated with standard tasks and cleaning the scope. We are therefore adjusting the time for this equipment item to 97 minutes. We continue to believe that 2 minutes represents the typical time required to prepare the specimen and are not adjusting the time. We agree with commenters that more than 1 pair of gloves may be required; however, since a biopsy is not required in all cases, we believe that 2 pairs of gloves accounts for the resources used in furnishing the typical service. Finally, we continue to believe that 3 containers represent the typical resources used in furnishing this procedure

given the small size of the lesions. After considering the comments received, we are finalizing the CY 2013 interim final direct PE inputs for CPT code 52224 as established with the additional refinement of adjusting the equipment time to account for cleaning the scope, and adding one pair of gloves, as noted above.

In establishing interim final direct PE inputs for CY 2013, we refined the AMA RUC's recommendation for CPT code 52287 by adjusting the time for the clinical labor activity "assist physician in performing procedure" from 20 minutes to 21 minutes to conform to the physician intraservice time, and refining the equipment time to reflect the typical use exclusive to the patient.

<u>Comment</u>: The AMA RUC stated that its original submission to CMS contained 21 minutes for this clinical labor activity. Another commenter noted that the times allocated to preservice clinical labor tasks were missing in the nonfacility setting. Another commenter stated that the equipment time should include the time for all of the standard clinical labor tasks.

Response: We note that the AMA RUC and CMS agree on the appropriate number of minutes to assign to the clinical labor service period to account for "assist physician." Regarding the preservice clinical labor tasks, we note that the AMA RUC did not recommend preservice clinical labor time for these tasks in the nonfacility setting, and that such inputs are not standard for 000-day global services. With respect to equipment time, we agree with commenters that the equipment time for all equipment in this procedure should include time for all of the standard clinical labor tasks, with the exception of the time allocated for cleaning of the scope. The times for the equipment items included in CPT code 52287 already include all of these tasks, with the exception of "fiberscope, flexible, cystoscopy" (ES018). We are adjusting time for the scope from 76 to 78 minutes to align the equipment time with that of the standard clinical labor tasks.

After considering the comments received, we are finalizing the CY 2013 interim final direct PE inputs for CPT code 52287 as established with the additional refinement of adjusting the equipment time as noted above.

(13) Transurethral Destruction of Prostate Tissue (CPT Code 53850)

In establishing interim final direct PE inputs for CY 2013, we refined the AMA RUC's recommendation for CPT code 53850 by refining equipment time to reflect typical use exclusive to the patient.

<u>Comment</u>: A commenter stated that the equipment time should include the time for all of the standard clinical labor tasks.

Response: We agree with the commenter that the equipment time for all equipment in this procedure should include time for all of the standard clinical labor tasks, and we are allocating the entire service period of 99 minutes for "stretcher, endoscopy" (EF020), "table, instrument, mobile" (EF027), "TUMT system control unit" (EQ037), and "ultrasound unit, portable" (EQ250), which are used during the service period only. In addition, we are allocating 169 minutes for items used during both the service period and postservice period, which are "table, power" (EF031) and "light, exam" (EQ168), to account for the both the service period and postservice period.

We also refined the AMA recommendation for this code by not assigning additional clinical labor minutes for non-standard clinical labor tasks described as "setup ultrasound probe," "setup TUMT machine," and "clean TUMT machine."

<u>Comment</u>: The same commenter also stated that the clinical labor tasks were necessary because extra time was required.

Response: We do not agree that the time for these clinical labor tasks is reflective of typical resource costs involved in furnishing the service. For this procedure the assigned clinical labor time already includes the standard number of minutes for set-up and clean-up, and the commenter provided no information justifying a deviation from these standard times for this procedure.

<u>Comment</u>: A commenter stated that there is no preservice clinical staff time assigned for the nonfacility, and that the clinical labor time should account for tasks such as "setting up the room," "greeting patient," and "position patient prior to the procedure."

Response: The clinical labor tasks referred to by the commenter are tasks generally included in service period activities; the preservice clinical staff time that is included when the procedure is done in

the facility includes scheduling and coordination services that are unique to procedures furnished in facility settings. The service period time for this procedure includes minutes allocated for clinical labor tasks such as "greet patient," "provide gowning," "ensure appropriate medical records are available," and "prepare and position patient." Therefore, we are not making a change at this time and are finalizing the CY 2013 interim final direct PE inputs for CPT code 53850, including the clinical labor tasks, as established.

(14) Nervous System: Extracranial Nerves, Peripheral Nerves, and Autonomic Nervous System (CPT Code 64615)

In establishing interim final direct PE inputs for CY 2013, we accepted the AMA RUC's recommendation for CPT code 64615 (Injection of chemical for destruction of facial and neck nerve muscles).

<u>Comment</u>: A commenter questioned why this service had only 3 minutes of postservice clinical labor time, while other codes in the family have 27 or 30 minutes.

Response: The apparent discrepancy between CPT code 64615 and the other codes in the family results because CPT 64615 does not have any post-operative visits in the global period while the other codes in the family have post-operative visits. Specifically, the 30 minutes of postservice clinical labor time in 64612 are allocated specifically for the post-operative visits. After consideration of public comment, we are finalizing the CY 2013 interim final direct PE inputs for CPT code 64615 as established.

(15) Diagnostic Radiology: Abdomen and Pelvis (CPT Codes 72191, 72192, 72193, 72194, 74150, 74160, 74170, 74175, 74176, 74177, 74178)

In establishing interim final direct PE inputs for CY 2013, we reviewed the direct PE inputs for all of the abdomen, pelvis, and abdomen/pelvis combined CT codes. For each set of codes, we established a common set of disposable supplies and medical equipment. We established clinical labor minutes that reflect the fundamental assumption that the component codes should include a base number of minutes for particular tasks, and that the number of minutes in the combined codes should reflect

efficiencies that occur when the regions are examined together. Among other refinements, we adjusted the intraservice time for CPT codes 72194, 74160, and 74177 by 2 minutes, 4 minutes, and 6 minutes respectively.

<u>Comment</u>: Commenters stated that more information was required about from where CMS decreased the minutes from the service period for CPT codes 72194, 74160, and 74177.

Response: We refined the minutes in the service period such that the aggregate number of clinical labor minutes reflected in the direct PE input database and used to develop PE RVUs was consistent within this family of codes. We believe that the aggregate clinical labor time in each clinical service period (preservice period, service period, and postservice period) or aggregate number of minutes for particular equipment items that reflects the total typical resource use is more important than the minutes associated with each clinical labor task, which are a tool used by the AMA RUC to develop their recommendations. We hope that in reviewing future services, commenters consider the aggregate clinical labor time as well, recognizing that it is the aggregate time that ultimately has implications for payment. Finally, we welcome comments that address the appropriateness of the number of clinical labor minutes in each service period and the number of equipment minutes for each service.

In this refinement process, we also removed supply item "needle, 18–27g" (SC029) and replaced it with "needle, 14–20g, biopsy" (SC025) for CPT codes 72193, 72194, 74160, and 74170.

<u>Comment</u>: Commenters stated that the biopsy needle (SC025) was not appropriate for these services, and that supply item "needle, 18-27g" (SC029) would be more appropriate. In addition, commenters noted that the "film processor" (ED024) is in use during a portion of the service.

Response: We agree with commenters that the "needle, 18-28g" (SC029) is more appropriate for these services, and that the film processor should be included for these codes. We are adjusting the direct PE inputs to include the needle and film processor in CPT codes 72193, 72194, 74160, and 74170.

In refining the direct PE inputs, we also substituted a radiologic technologist for a CT technologist for CPT codes 72191 and 74175, and removed the clinical labor time for "Retrieve prior

appropriate imaging exams and hang for MD review, verify orders, review the chart to incorporate relevant clinical information" from 72191, 74170, and 74175.

<u>Comment</u>: Commenters stated that a CT technologist was the typical clinical labor type for these CT procedures. Commenters also objected to the removal of recommended minutes based on the clinical labor activity "Retrieve prior appropriate imaging exams and hang for MD review, verify orders, review the chart to incorporate relevant clinical information" from CPT codes 72191, 74170, and 74175, and to the reduction of preservice and intraservice clinical labor time in this family of codes.

Response: Based on the information provided by commenters, we agree that CPT codes 72191 and 74175 should include a CT technologist rather than a radiologic technologist for CPT codes 72191 and 74175 because the CT technologist is typical. However, we do not agree that the clinical labor time should be changed per the commenters' request, as we continue to believe that these tasks are already captured in the preservice clinical labor time. We refer readers to the CY 2013 PFS final rule with comment period (77 FR 69073) for a discussion of the development of a standard allocation of inputs for these families of codes.

For CPT code 72191, we refined the time for equipment item "room, CT" (EL007) to 40 minutes.

<u>Comment</u>: Commenters stated that the CT room time for should be at least 43 minutes to include time for cleaning the room.

Response: We agree with commenters that the time for the CT room should be 43 minutes to include the standard clinical labor tasks for highly technical equipment, including cleaning the room.

After considering the comments received, we are finalizing the CY 2013 interim final direct PE inputs for CPT codes 72193, 72194, 73221, 73721, 74150, 74160, 74170, 74175, 74176, and 74177 as established with the additional refinements of the supply item, changes to clinical labor staff type, and equipment time noted above.

(16) Diagnostic Ultrasound: Transvaginal and Transrectal Ultrasound (CPT Codes 76830 and 76872)

In establishing interim final direct PE inputs for CY 2013, we refined the AMA RUC's recommendation for CPT code 76830 by removing the equipment item "room, ultrasound, general"

(EL015) and replacing it with individual items including a portable ultrasound unit. Comment: A commenter noted that a panel of obstetrician/gynecologists, a specialty that frequently furnishes this service, indicated that a dedicated ultrasound room was used.

Response: Based on the comments we received, we agree that it would be more appropriate to allocate a general ultrasound room for this procedure rather than a portable ultrasound unit and accompanying items. We are including the ultrasound room as a direct PE input for CPT code 76830.

In refining the inputs for CPT code 76830, we also removed "film alternator (motorized film viewbox)" (ER029), "Surgilube lubricating jelly" (SJ033), and "film processor, dry, laser" (ED024).

<u>Comment</u>: Another commenter stated that the film alternator and Surgilube lubricating jelly are required; however, the specialty that most frequently furnishes the service stated that they did not use either of these items.

Response: We continue to believe that neither the film alternator nor the lubricating jelly should be included for this service as, and after considering the comments from the specialty that most frequently furnishes the service, we agree that these are not used in the typical case.

After considering the comments received, we are finalizing the CY 2013 interim final direct PE inputs for CPT code 76830 as established with the additional refinement of allocating a general ultrasound room and removing individual inputs related to a portable ultrasound unit.

In establishing interim final direct PE inputs for CY 2013, we refined the AMA RUC's recommendation for CPT code 76872 by adjusting the equipment time to reflect the typical use exclusive to the patient, and removing clinical labor tasks, "obtain vital signs," and "prepare ultrasound probe" from the preservice period; removing "obtain vital signs" from the service period; and removing supply items "drape, sterile, for Mayo stand" (SB012), "iv tubing (extension)" (SC019), "lidocaine 2% jelly, topical (Xylocaine)" (SH048), "alcohol isopropyl 70%" (SJ001), "lubricating jelly (K-Y) (5gm uou)" (SJ032), "glutaraldehyde 3.4% (Cidex, Maxicide, Wavicide)" (SM018), "glutaraldehyde test strips (Cidex, Metrex)" (SM019), and "sanitizing cloth-wipe (surface, instruments, equipment)" (SM022).

<u>Comment</u>: Commenters indicated that the equipment time allocated for this procedure should be 68 minutes to reflect the time that the equipment is unavailable for other patients.

Response: We agree with commenters that the equipment time for all equipment in this procedure should include time for all of the standard clinical labor tasks in the service period, so we are allocating 42 minutes for those equipment items.

<u>Comment</u>: Commenters noted that it is necessary to obtain vital signs prior to the service, and that the supplies were necessary for a variety of purposes outlined in the comment.

Response: We do not agree that it is necessary to obtain vital signs in the preservice period in order to determine if the patient becomes hypotensive during the service period, but agree that obtaining vital signs in the service period is necessary. We note that we have standard setup times for equipment and do not generally allocate separate time for preparing individual pieces of equipment. After considering the information provided by the commenters, we are persuaded that the supplies that were removed are necessary for the procedure. Therefore, we are including 3 additional minutes in the service period and reinstating the supplies that we removed from the procedure in establishing interim final direct PE inputs.

After considering comments received, we are finalizing the CY 2013 interim final direct PE inputs for CPT code 76872 as established with the additional refinement of adjusting equipment time and incorporating supply items as noted above.

(17) Radiation oncology: Medical Radiation Physics, Dosimetry, Treatment Devices, and Special Services (CPT Code 77301)

In establishing interim final direct PE inputs for CY 2013, we refined the AMA RUC's recommendation for CPT code 77301 by removing equipment item "computer system, record and verify" from the service, adjusting the equipment time for "treatment planning system, IMRT (Corvus w-Peregrine 3D Monte Carlo)" from 376 to 330, among other refinements previously discussed in the context of our discussion of general refinements.

<u>Comment</u>: Commenters indicated that the minutes used for the computer system are not captured elsewhere and should be included in the service, and that there is physician time independent of clinical staff time for the treatment planning system.

Response: The computer system was not previously an input for this service, and the commenter did not provide sufficient information or evidence for us to conclude that there should be a change. We also note that this service has both a technical and professional component; the professional component has no inputs, and the equipment time associated with the physician time is not appropriately placed in the technical component. Thus, the equipment time is allocated for the technical component only.

After considering public comments, we are finalizing the CY 2013 interim final direct PE inputs for CPT code 77301 as established.

(18) Nuclear Medicine: Diagnostic (CPT Code 78072)

In establishing interim final direct PE inputs for CY 2013, we were unable to price the new equipment item "gamma camera system, single-dual head SPECT/CT" for CPT code 78072 (Parathyroid planar imaging (including subtraction, when performed); with tomographic (SPECT), and concurrently acquired computed tomography (CT) for anatomical localization)) since we did not receive any paid invoices. Because the cost of the item that we were unable to price is disproportionately large relative to the costs reflected by remainder of the recommended direct PE inputs, we contractor priced the technical component of the code for CY 2013, on an interim basis, until the newly recommended equipment item could be appropriately priced.

<u>Comment</u>: A commenter indicated that it would provide necessary documentation so that CMS can establish a price for the new SPECT/CT equipment item associated with CPT code 78072. We received 4 paid invoices for the SPECT/CT equipment.

Response: Out of the four invoices we received, we were only able to use one of them to price the equipment because the other three included training and other costs as part of the overall equipment price. Since training and these other costs are not considered part of the price of the equipment in the current PE methodology, we are unable to use invoices when these items are not separately priced on the

invoice. Based on the invoice that met our criteria, this equipment is priced at \$600,272. We are assigning 92 minutes based on our standard allocation for highly technical equipment, to include "prepare room, prepare and position patient, administer radiopharmaceutical, acquire images, complete diagnostic forms, and clean room." After reviewing the comments received, we are establishing interim final direct PE inputs for CPT code 78082 and, rather than contractor price the code as we did in 2013, we are pricing this code under the PFS on an interim final basis for CY 2014.

(19) Pathology and Laboratory: Chemistry (CPT Code 86153)

In establishing interim final direct PE inputs for CY 2013, we refined the AMA RUC's recommendation for CPT code 86153 (Cell enumeration using immunologic selection and identification in fluid specimen (eg, circulating tumor cells in blood)) by valuing the service without direct practice expense inputs.

<u>Comment</u>: Commenters requested that we include direct PE inputs for CPT code 86153, explaining that in the majority of cases, CPT code 86152 is submitted without an accompanying 86153 code. Commenters noted that there are clinical labor tasks furnished by a laboratory technician for this service.

Response: CPT code 86153 is a professional component-only CPT code that is a "clinical laboratory interpretation service," which is one of the current categories of PFS physician pathology services. For this category of services, only services billed with a "26" modifier may be paid under the PFS; the technical component of these services is paid under the Clinical Lab Fee Schedule (CLFS). Generally, under the PFS, RVUs for services billed with a "26" modifier do not include direct PE inputs, since the development of the RVUs for such codes incorporate all associated direct PE inputs in the RVUs for the technical component of the service. When the corresponding laboratory service is billed under the CLFS, the payment accounts for the resource costs involved in furnishing the laboratory service, including the kinds of costs described by the items in the direct PE input database. In addition, we do not believe that it would serve appropriate relativity to include direct PE inputs for professional component services only when the corresponding technical component payment is made through a

different Medicare payment system. After consideration of public comment, we are finalizing our CY 2013 interim final valuation of this service as established.

(20) Pathology and Laboratory: Surgical Pathology (CPT Codes 88300, 88302, 88304, 88305, 88307, 88309)

In establishing interim final direct PE inputs for CY 2013, we refined the AMA RUC's recommendation for CPT codes 88300, 88302, 88304, 88305, 88307, and 88309 (Surgical Pathology, Levels I through VI), by not including new supply items "specimen, solvent, and formalin disposal cost," and "courier transportation costs" and new equipment items called "equipment maintenance cost," "Copath System with maintenance contract," and "Copath software." We stated in the CY 2013 final rule with comment period that we would consider additional information from commenters regarding whether the Copath computer system and associated software should be considered a direct cost as medical equipment associated with furnishing the technical component of these surgical pathology services. We stated that we were especially interested in understanding the clinical functionality of the equipment in relation to the services being furnished. We also sought additional public comment regarding the appropriate assumptions regarding the direct PE inputs for these services, as well as independent evidence regarding the appropriate number of blocks to assume as typical for each of these services. We requested public comment regarding the appropriate number of blocks and urged the AMA RUC and interested medical specialty societies to provide corroborating, independent evidence that the number of blocks assumed in the current direct PE input recommendations is typical prior to finalizing the direct PE inputs for these services.

<u>Comment</u>: Commenters generally rejected the notion that the items CMS did not accept for this family of codes are indirect costs and asked for a basis for CMS's statement that disposal costs are accounted for in the indirect PE allocation. A commenter asserted that it is extremely rare for CMS to not accept direct PE inputs recommended by the AMA RUC.

Response: As we noted above and in the CY 2014 PFS proposed rule (78 FR 43292), within the PE methodology all costs other than clinical labor, disposable supplies, and medical equipment are

considered indirect costs. We note that we frequently refine direct PE recommendations from the AMA RUC and address these refinements through rulemaking. Below, we respond to the specific statements by commenters regarding particular items not accepted as direct inputs.

Comment: Commenters stated that specimen, solvent, and formalin disposal costs are variable costs that can be allocated to individual specimens, and noted that these costs are not captured in surveys of indirect costs used for the PFS. Commenters asserted that these costs are proportional to the number of specimens processed each day, and are directly attributable to each case by specimen size and the number of tissue blocks associated with that specimen. Commenters pointed to several items in the direct PE database that they believed were anomalous to the specimen, solvent, and formalin disposal costs that we did not accept.

Response: In the CY 2014 PFS proposed rule (78 FR 43293), we addressed the items in the direct PE database brought to our attention by the commenters. There, we clarified that we believe that a disposable supply is one that is attributable, in its entirety, to an individual patient for a particular service. We clarified that we believe that supply costs related to specimen disposal attributable to individual services may be appropriately categorized as disposable supplies, but that specimen disposal costs related to an allocated portion of service contracts that cannot be attributed to individual services should not be incorporated into the direct PE input database as disposable supplies. As we address in section II.B. of this final rule, all costs other than clinical labor, disposable supplies, and medical equipment should be considered indirect costs in order to maintain relativity within the PE methodology. We believe that there are a wide range of costs allocable to individual services that are appropriately considered part of indirect cost categories for purposes of the PE methodology.

Comment: Commenters argued that courier transportation costs are directly allocable to individual beneficiary specimens, and represent a significant practice expense. One commenter stated, "Although more than one specimen may be included in a courier run, still there is a cost per specimen" and asserted that the indirect PE costs allocated to CPT code 88305 do not adequately account for the sizeable expense of couriers.

Response: Again, we maintain that all costs other than clinical labor, disposable supplies, and medical equipment should be considered indirect costs to maintain relativity within the PE methodology. In addition to not meeting that criterion to be considered direct PE, the commenter pointed out that more than one specimen may be included in a courier run, so that the cost of courier services does not meet the additional criterion of being "attributable, in its entirety, to an individual patient for a particular service." We acknowledge the commenters' concern that the indirect costs allocated to CPT code 88305 may not equate to the indirect costs associated for every instance a service described by that code is furnished. However, we note that the practice expense methodology is applied consistently throughout the fee schedule, and that the nature of indirect costs is such that the costs allocated to an individual procedure are an estimate of the relative costs associated with the typical procedure reported with a particular code, and are not intended to account for those costs on a line item basis for each instance the code is reported.

<u>Comment</u>: Commenters argued that the maintenance costs are in fact variable costs in that the costs are proportional to specimen volume. Commenters acknowledged the 5% equipment maintenance factor that is figured into the costs of equipment inputs to the PE methodology, but argued that pathology laboratories have several equipment items that require more frequent maintenance (in the range of 10% - 12%). Commenters requested that we establish specialty-specific maintenance factors.

Response: We believe that the nature of many equipment items across the fee schedule is such that the required maintenance would relate, at least in part, to the volume of procedures furnished using the equipment. We note that the established PE methodology does not generally account for either additional costs incurred or efficiencies gained when services are furnished in atypical volumes. The equipment maintenance factor is intended to represent the typical cost per minute associated with a particular piece of equipment. At this time, our PE methodology does not accommodate equipment maintenance factors that vary by specialty.

<u>Comment</u>: Commenters provided descriptions of the CoPath system, indicating that the system provides procedure support that assists labs with specimen management and tracking, report generation, record storage, workflow automation, management reporting and quality assurance functions and support.

Commenters stated that the CoPath system is a stand-alone system that must be interfaced with the main electronic health care record system, and is unique to pathology and only used by pathology. The CoPath system is required for labs to assign each specimen its unique identifier and associate it with other specimens from the same patient, as well as track the course of the entire process.

Commenters also explained that the CoPath system is an advanced pathology information management system for storing and reporting pathology information and accommodates clinical disciplines including surgical pathology, cytology, histology, and autopsy. CoPath manages the integrity of specimen accession and processing, and provides patient history review, pathology text entry, support for diagnostic coding using the CAP SNOMED database, report generation, case review and sign out, and retrieval for subsequent purposes. It also assists in inputting blocks and interfaces with cassette and slide labelers, querying database for cases, patient histories, and reducing workload. Commenters compared the Picture Archiving and Communication System (PACS) system for radiologists to the CoPath or equivalent system for pathology.

One commenter argued that the clerical and administrative functionality support by a laboratory information system is immaterial to the direct costs associated with its more prominent utility as the clinical information infrastructure for anatomic pathology laboratories.

Response: We asked for comments to help with our understanding of the clinical functionality of the equipment in relation to the services being furnished. We appreciate the explanations provided, as well as the comparison to the PACS system for radiologists. Based on our review of the comments received, we understand that this information management system is used for a variety of administrative and clerical functions, as well as clinical support functions. Tools that facilitate the similar functionality for other services, such as the cognitive work involved in the professional component, are considered indirect costs under the PFS. For instance, across services furnished by a range of physician specialties, many items that support clinical decision-making are considered indirect costs, irrespective of their utility and are not included in the PE methodology as direct costs. Instead, they are part of the indirect category

of resource costs. As a general principle, for this reason, we do not believe that information management systems are appropriately characterized as direct costs.

Furthermore, we believe that the relativity within the PE methodology would be undermined by including these kinds of items as medical equipment only for particular kinds of services. We believe that, were we to reconsider the categorization of clinical information systems for this particular kind of service, it would be necessary to reconsider the categorization of resource costs of other clinical information systems used across PFS services. Therefore, we continue to believe that the CoPath system is best characterized as an indirect cost that is captured in the indirect cost allocation.

<u>Comment</u>: One commenter suggested that the labor cost of the histotechnologist is closer to 50 cents per minute, rather than the 37 cents per minute used in the PE direct inputs database.

Response: We did not change the labor cost for histotechnologists in the CY 2013 final rule with comment period. We note, however, that the prices associated with the labor codes derive from data from the Bureau of Labor Statistics, and we will consider the appropriate time to update all labor category costs in the PE direct inputs database for future rulemaking.

<u>Comment</u>: Commenters disputed the assertion that there is a "typical" case for CPT code 88305, given that there are wide variations in the types of tissues being biopsied.

Response: Under the PFS, services are priced based on the typical case. We continue to seek the best information regarding the inputs involved in furnishing the typical case.

<u>Comment</u>: Commenters expressed concern that CMS asked the AMA RUC to review CPT code 88305 based on the assertion of a single stakeholder that the clinical vignette used to identify the PE inputs was not typical.

Response: As indicated in section II.C.2 of this final rule with comment period, we note that we generally do not identify a code as potentially misvalued solely on the basis of individual assertions. On the contrary, when stakeholders bring information to our attention, it is subject to internal review to determine whether the code would appropriately be proposed as a potentially misvalued code, and we offer the public the opportunity to comment prior to finalizing a code as potentially misvalued. We

followed our standard process in evaluating CPT code 88305 as potentially misvalued and reached the conclusion that it was appropriate the refer the service to the AMA RUC. Therefore, we do not agree with commenters that we asked the AMA RUC to review this service based solely on information provided by a single stakeholder.

Comment: Some commenters provided information regarding the number of blocks that is typical for 88305. An association representing pathologists argued that there is no typical case for 88305, and provided several vignettes to illustrate the variation based on the type of tissue being biopsied. The association also presented findings from one data collection effort involving several specialty societies that suggested that the typical number of blocks may be as high as four. However, the association supported the AMA RUC's recommendation of two blocks as most likely to represent the typical case. Other commenters indicated that a review of hundreds of cases from multiple institutions indicated that the typical, or average, case of 88305 requires one block, not two, and that 92% of cases including pathology, skin pathology, surgical pathology, urologic pathology, cell blocks, and bone marrow cases required one block. Another medical specialty indicated that more than two slide-blocks are routinely required, and requested the use of a modifier for 88305 for those services that routinely require more than two slide-blocks. Another commenter requested that we stratify payment based on the number of blocks. Another commenter suggested that the AMA RUC's recommended number of clinical labor minutes for 88305 underestimates the amount of clinical labor time associated with the typical service described by the code.

Response: Based on the wide range of views expressed in comments, it is difficult to determine the appropriate number of blocks to use in establishing direct PE inputs for CPT code 88305. At this time, because we do not have strong evidence to conclude that a change should be made, are maintaining these values. However, we will continue to seek better information to permit consideration of the appropriate number of blocks, and the appropriate direct PE inputs for this code. We are not establishing a modifier to differentiate the number of blocks since there is not a current billing mechanism to make adjustments based on the number of blocks used when a code is reported.

Comment: One commenter argued that the practice expense RVU for CPT code 88305 is insufficient for a tissue exam with two blocks and certainly insufficient for those exams that require more than the two blocks and slides than are accounted for in the AMA RUC's vignette. The commenter argued that even though many tissue biopsies may use an average of two blocks, the valuation of this service does not account for the many kinds of biopsies that use more than two blocks. Another commenter argued that the payment will no longer allow "profits" for 1-2 block specimens to offset the "losses" from specimens that require a larger number of blocks.

Response: We acknowledge the commenter's concern that the valuation of this service is based on two blocks when some services require a greater number of blocks. However, this circumstance is not inconsistent with the established PE methodology, which accounts for the relative resources involved in furnishing a typical case for a particular HCPCS code. We acknowledge that there are cases that use higher than typical resources, and that there are also cases that use lower than typical resources. As a general principle, we do not believe that the direct inputs associated with a particular PFS service should be established or maintained to result in payment rates that might offset outlier cases for that service or support practice expenses for practitioners who furnish lower-paid services.

Furthermore, we note that we continue to receive feedback regarding the appropriate coding and code descriptors for surgical pathology for the prostate needle biopsy services. We believe that revising the code descriptors to ensure that all prostate needle biopsy services with 10 or more specimens are described by the G-codes may facilitate broader consensus regarding the typical resource costs for 88305. Therefore, for clarity, we are revising the CY 2014 descriptors for these HCPCS codes to include the phrase "any method" following "sampling."

The revised HCPCS code descriptors for microscopic examination for prostate biopsy are as follows: G0416 (Surgical pathology, gross and microscopic examination for prostate needle biopsies, any method; 10-20 specimens), G0417 (Surgical pathology, gross and microscopic examination for prostate needle biopsies, any method; 21-40 specimens), G0418 (Surgical pathology, gross and microscopic examination

for prostate needle biopsies, any method; 41-60 specimens) and G0419 (Surgical pathology, gross and microscopic examination for prostate needle biopsies, any method; greater than 60 specimens).

After consideration of public comments received, we are finalizing the CY 2013 interim final direct PE inputs for CPT codes 88300-88309 as established.

(21) Pathology and Laboratory: Cytopathology (CPT Codes 88120 and 88121)

In the PFS final rule with comment period, we addressed comments from stakeholders who suggested that CMS increase the price of the supply "UroVysion test kit" (SA105) by building in an "efficiency factor" to account for the kits that are purchased by practitioners and used in tests that fail. The stakeholders provided documentation suggesting that a certain failure rate is inherent in the procedure.

We indicated that the prices associated with supply inputs in the direct PE input database reflect the price per unit of each supply. Since the current PE methodology relies on the inputs for each service reflecting the typical direct practice expense costs for each service, and the supply costs for the failed tests are not used in furnishing PFS services, we do not believe that the methodology accommodates a failure rate in allocating the cost of disposable medical supplies. Therefore, we did not adjust the price input for "UroVysion test kit" (SA105) in the direct PE input database.

<u>Comment</u>: Commenters disagreed with our decision, stating that these are valid expenses and that the inherent failure rate is commonly due to factors beyond the control of the laboratory or quality of equipment. Further, commenters pointed out that these costs are not reflected in overhead costs, and should therefore be included in direct practice expense inputs.

Response: Because the current PE methodology relies on the inputs used in furnishing each service, reflecting the typical direct practice expense costs for each service, we continue to believe that the price of the supply kit should not reflect any failure rate. After consideration of public comment, we are finalizing the CY 2013 interim final direct PE inputs for CPT codes 88120 and 88121 as established.

(22) Immunotherapy Injections (CPT codes 95115 and 95117)

In establishing interim final direct PE inputs for CPT codes 95115 and 95117, we refined the AMA RUC's recommendation by removing equipment item "refrigerator, vaccine, commercial grade, walarm lock."

Comment: Commenters indicated that injectable materials need to be refrigerated, and thus the refrigerator should be included for this service.

Response: As previously noted, equipment that is used for multiple procedures at once is considered an indirect cost. In future rulemaking, we anticipate reviewing our files for consistency across practice expense inputs in this regard. After consideration of comments received, we are finalizing the CY 2013 interim final direct practice expense inputs for CPT codes 95115 and 95117 as established. (23) Neurology and Neuromuscular Procedures: Intraoperative Neurophysiology (CPT Codes 95940, 95941 and HCPCS Code G0453)

In establishing payment for intraoperative neurophysiology (95940 and G0453) for CY 2013, we did not accept the AMA RUC direct PE input recommendations, since we do not believe that these services are furnished to patients outside of facility settings.

Comment: A commenter noted that hospitals previously owned all of the equipment and supplies and employed the technicians for intraoperative monitoring. The commenter asserted that, currently, hospitals often use "mobile services" to furnish these monitoring procedures, and thus there should be technical component RVUs for these services.

Response: The structure of monitoring businesses and the arrangements made with hospitals are not a factor in determining the inputs typical to a particular service. Since this service is furnished in a facility, we have not included direct PE inputs for this service. We continue to believe that this service should be priced without direct PE inputs because when a service is furnished in the facility setting, the equipment, supplies, and labor costs of the service are considered in the calculation of Medicare payments made to the facility through other Medicare payment systems. After consideration of comments received, we are finalizing the CY 2013 interim final direct PE inputs for 95940 and G0453 as established.

(24) Neurology and Neuromuscular Procedures: Sleep Medicine Testing (CPT Codes 95782, 95783)

In establishing interim final direct PE inputs for CY 2013, we refined the AMA RUC's recommendation for CPT codes 95782 (Polysomnography, younger than 6 years, 4 or more) and 95783 (Polysomnography, younger than 6 years, w/cpap) by reducing time associated with "Measure and mark head and face. Apply and secure electrodes to head and face. Check impedances. Reapply electrodes as needed" and "apply recording devices" and removing equipment item "crib" for use in these services. We stated that we did not believe a crib would typically be used in this service, and we incorporated the bedroom furniture including a hospital bed and a reclining chair as typical equipment for this service.

Comment: Commenters disagreed, stating that it takes additional time to perform these clinical labor tasks for a child, and that we should assign 30 minutes to the "measure and mark head and face" task and 25 minutes to the "apply recording devices" task. Commenters also indicated that the crib is used in the typical case, while the parent uses the hospital bed to remain close to the child. We also received a paid invoice for the equipment item "crib."

Response: After additional clinical review, we agree with commenters' explanation that the additional clinical labor minutes are required when furnishing these services to children. Therefore, we are allocating an additional 5 minutes for each of these tasks, so that 25 minutes are allocated based on the clinical labor task called "Measure and mark head and face. Apply and secure electrodes to head and face. Check impedances. Reapply electrodes as needed" and 20 minutes are allocated for the task "apply recording devices." Based on the information provided by commenters, we agree that the equipment item "crib" should be included for CPT codes 95782 and 95783. We are pricing the equipment item "crib" at \$3,900 based on the invoice received. After consideration of the comments received, we are finalizing the CY 2013 interim final direct PE inputs for 95782 and 95783 as established with the additional refinement of adjusting the clinical labor time and incorporating the "crib" discussed above.

(25) Neurology and Neuromuscular Procedures: Electromyography and Nerve Conduction Tests (CPT codes 95907, 95908, 95909, 95910, 95911, 95912, 95913, and 95861)

In establishing interim final direct PE inputs for CY 2013, we refined the AMA RUC's recommendation for CPT code 95861 by adjusting the time for the clinical labor activity "assist physician in performing procedure" from 19 minutes to 29 minutes to conform to physician time.

<u>Comment</u>: Commenters brought to our attention that this refinement was inaccurate, in that the AMA RUC recommendation included 29 minutes for this labor activity.

Response: We agree with commenters that this refinement was inaccurate and acknowledge the administrative discrepancy in the refinement table. We note that this had no impact on payment rates, since there was no corresponding discrepancy in the direct PE input database. After considering comments received, we are finalizing the CY 2013 interim final direct PE inputs for CPT code 95861 as established.

We also refined the AMA RUC's recommendation for CPT codes 95907, 95908, 95909, 95910, 95911, 95912, and 95913 by substituting non-sterile gauze for sterile gauze, and removing surgical tape and electrode gel.

<u>Comment</u>: Commenters indicated that sterile gauze is required because the skin is cleansed before the procedure with vigorous scrubbing that often can produce minor bleeding, and that tape is required because the electrodes may not stick well when testing patients who have used lotions or creams prior to testing. Finally, the electrode gel is required to maximize conductivity, especially in patients who have used lotions or creams prior to testing.

Response: We agree with commenters that the sterile gauze and tape should be included for this service. However, since the disposable electrode pack includes pre-gelled electrodes, we do not believe it is typical that electrode gel is also used in this procedure. After consideration of public comments, we are finalizing the CY 2013 interim final direct practice expense inputs for CPT codes 95907 – 95913 as established, with the additional refinement of including the sterile gauze and tape.

(26) Neurology and Neuromuscular Procedures: Autonomic Function Testing (CPT Codes 95921, 95922, 95923, and 95924)

In establishing interim final direct PE inputs for CY 2013, we refined the AMA RUC's recommendation for CPT codes 95921 and 95922 by removing the preservice clinical labor tasks, and adjusting the monitoring time following the procedure from 5 to 2 minutes for 95921, 95922, 95923, and 95924.

<u>Comment</u>: Commenters stated that the patient requires assistance following the tests; therefore, additional time for monitoring the patient is necessary and should be added to the number of clinical labor minutes in the service period.

Response: CMS clinical staff reviewed the information presented by commenters and found no evidence that 2 minutes did not represent the typical resources involved in furnishing the service for CPT codes 95921, 95922, 95923, and 95924.

In refining CPT codes 95921, 95922, 95923, and 95924, we refined the equipment time to reflect the typical use exclusive to the patient.

<u>Comment</u>: Commenters stated that extra time was required for the equipment so that the patient can lie still after the procedure to ensure that there are not negative side effects due to fluctuations in blood pressure.

Response: We agree with commenters' justification for allocating additional equipment minutes to account for the time that the patient is laying still after the procedure.

In refining CPT code 95923, we refined the clinical labor activity "assist physician" to 45 minutes.

<u>Comment</u>: Commenters stated that an additional 10 minutes of "assist physician" time was needed to assist the patient out of the machine and into the shower, since patients are extremely sweaty after the procedure.

Response: Assisting patients following the procedure is not part of the "assist physician" labor activity. Since this clinical labor activity was not specified in the AMA RUC recommendation, we do not believe this activity typically takes additional time over that already allotted to the procedure. After

considering public comments received, we are finalizing the CY 2013 interim final direct practice expense inputs for CPT codes 95921 – 95924 as established.

(27) Special Dermatological Procedures (CPT Codes 96920, 96921, 96922)

In establishing interim final direct PE inputs for CY 2013, we refined the AMA RUC's recommendation for CPT codes 96920, 96921, and 96922 by decreasing the time allocated to clinical labor activity "monitor patient following service/check tubes, monitors, drains" from 3 minutes to 1 minutes, and clinical labor activity "clean room/equipment by physician staff" from 3 minutes to 2 minutes.

<u>Comment</u>: Commenters objected to CMS's refinement of clinical labor tasks below the standard number of minutes allocated for these tasks.

Response: We agree with commenters that the standard number of AMA RUC-recommended minutes should be allocated for these tasks. After considering public comments received, we are finalizing the CY 2013 interim final direct practice expense inputs for CPT codes 96920, 96921, and 96922 with the additional refinement of adjusting the times allocated for the clinical labor activities noted above.

(28) Psychiatry (CPT codes 90791, 90832, 90834, and 90837)

As we addressed in the CY 2013 PFS final rule (77 FR 69075), the AMA RUC submitted direct PE input recommendations in the revised set of codes that describe psychotherapy services. These recommendations included significant reductions to the direct PE inputs associated with the predecessor codes. For most of the new codes, we accepted these recommended reductions in direct practice expense. This was consistent with our general approach of maintaining the existing values for these services given that many practitioners who furnished these services prior to CY 2013 would report concurrent medical evaluation and management services (which have practice expense values that will offset the differences in total PE values between the new and old psychotherapy codes). However, for practitioners who do not furnish medical E/M services, there were no corresponding PE value increases to offset the recommended reductions. Therefore, instead of accepting the recommended direct PE inputs for the new CPT codes that

describe services primarily furnished by practitioners who do not also report medical E/M services, for CY 2013, we crosswalked the 2012 PE RVUs from the predecessor codes. This crosswalk used the CY 2012 year fully-implemented PE RVUs established for CPT codes 90791 (Psychiatric diagnostic evaluation), 90832 (Psychotherapy, 30 minutes with patient and/or family member), 90834 (Psychotherapy, 45 minutes with patient and/or family member), and 90837 (Psychotherapy, 60 minutes with patient and/or family member).

<u>Comment</u>: Several commenters pointed out that by crosswalking the PE RVUs from predecessor codes, CMS created a rank order anomaly for CPT codes 90791 (Psychiatric diagnostic evaluation) and 90792 (Psychiatric diagnostic evaluation with medical services). These commenters urged CMS to issue a technical correction for CY 2013 and accept the AMA-RUC recommended inputs in developing PE RVUs for these services for CY 2014.

Response: We appreciate the commenters' concerns regarding rank order anomalies for these services. However, as we explained in establishing the interim final values for CY 2013, we believed that it was important to maintain approximate overall value for the family of services for the specialties involved, pending valuation of the whole set of codes for CY 2014. Now that we have considered the full family of codes for CY 2014 including the additional work RVUs, we agree with the commenters and believe that the AMA RUC- recommended direct PE inputs for the whole family of codes can be implemented. Given the significant change in PE RVUs and in the context of the whole family of services, the direct PE inputs for these services will be interim final and subject to comment for CY 2014.

<u>Comment</u>: In a comment to the CY 2014 proposed PFS rule, one commenter argued that the crosswalked PE RVUs for these services should be maintained due to the negative impact of the PE methodology on certain specialties, especially clinical psychologists. This commenter also suggested that the reductions in PE RVUs that would result from implementing the AMA RUC recommended direct PE inputs for CY 2014 would fully offset any increases in work RVUs for these services.

Response: We do not agree that the reductions in PE RVUs that result from the AMA RUC-recommended inputs fully offset the increases in overall payment for these services that results from

CMS' adoption of the AMA RUC-recommended work RVUs for most of the codes in this family.

However, we will consider the commenter's concerns regarding the effect of the PE methodology for specialties like clinical psychologists for future rulemaking.

(29) Transitional Care Management Services (CPT Codes 99495, 99496)

In establishing interim final direct PE inputs for CY 2013, we refined the AMA RUC recommendation by incorporating the clinical labor inputs for dedicated non-face-to-face care management tasks as facility inputs in addition to increasing clinical labor minutes for 99496.

Comment: The AMA RUC disagreed with CMS's refinement to include clinical labor minutes in the facility setting based on the assertion that the non-face-to-face care management tasks are critical to the codes and cannot be separated from the care coordination delivered by the clinical staff in the non-facility setting. The AMA RUC also suggested that several medical specialty societies also disagreed with the refinement to include clinical labor minutes in the facility setting, while one specialty society agreed with our refinement.

Response: After considering the rationale of the AMA RUC, we agree that only non-facility direct PE inputs should be included for these services. Therefore, we are finalizing the CY 2013 interim final direct PE inputs for 99495 and 99496 as established with the additional refinement of removing the facility direct PE inputs.

c. Finalizing CY 2013 Interim and Proposed Malpractice Crosswalks for CY 2014

In accordance with our malpractice methodology, we adjusted the malpractice RVUs for the CY 2013 new/revised codes for the difference in work RVUs (or, if greater, the clinical labor portion of the PE RVUs) between the source codes and the new/revised codes to reflect the specific risk-of-service for the new/revised codes. The interim final malpractice crosswalks were listed in Table 75 of the CY 2013 PFS final rule with comment period.

We received no comments on the CY 2013 interim final malpractice crosswalks and are finalizing them without modification for CY 2014. The malpractices RVUs for these services are reflected in Addendum B of this CY 2014 PFS final rule with comment period.

Consistent with past practice when the MEI has been rebased or revised we proposed to make adjustments to ensure that estimates of the aggregate CY 2014 PFS payments for work, PE and malpractice are in proportion to the weights for these categories in the revised MEI. As discussed in the II.A., the MEI is being revised for CY 2014, the PE and malpractice RVUs, and the CF are being adjusted accordingly. For more information on this, see section II.B. We received no comments specifically on the adjustment to malpractice RVUs.

d. Other New, Revised or Potentially Misvalued Codes with CY 2013 Interim Final RVUs Not Specifically Discussed in the CY 2014 Final Rule with Comment Period

For all other new, revised, or potentially misvalued codes with CY 2013 interim final RVUs that are not specifically discussed in this CY 2014 PFS final rule with comment period, we are finalizing for CY 2014, without modification, the CY 2013 interim final or CY 2014 proposed work RVUs, malpractice crosswalks, and direct PE inputs. Unless otherwise indicated, we agreed with the time values recommended by the AMA RUC or HCPAC for all codes addressed in this section. The time values for all codes are listed in a file called "CY 2014 PFS Physician Time," available on the CMS website under downloads for the CY 2014 PFS final rule with comment period at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.

- 3. Establishing CY 2014 Interim Final RVUs
- a. Establishing CY 2014 Interim Final Work RVUs

Table 27 contains the CY 2014 interim final work RVUs for all codes for which we received AMA RUC recommendations for CY 2014 and new G-codes created for CY 2014. These values are subject to public comment in this final rule with comment period. Codes for which work RVUs are not applicable have the appropriate PFS procedure status indicator in the relevant column. A description of all PFS procedure status indicators can be found in Addendum A. The column labeled "CMS Time Refinement" indicates for each code whether we refined the time values recommended by the AMA RUC or HCPAC.

The RVUs and other payment information for all CY 2014 payable codes are available in Addendum B. The RVUs and other payment information regarding all codes subject to public comment in this final rule with comment period are available in Addendum C. All addenda are available on the CMS website under downloads for the CY 2014 PFS final rule with comment period at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html. The time values for all CY 2014 codes are listed in a file called "CY 2014 PFS Physician Time," available on the CMS website under downloads for the CY 2014 PFS final rule with comment period at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.

TABLE 27: Interim Final Work RVUs for New/Revised/Potentially Misvalued Codes

HCPCS Code	Long Descriptor	CY 2013 Work RVU	AMA RUC/ HCPAC Recommended Work RVU	CY 2014 Work RVU	CMS Time Refinement
10030	Image-guided fluid collection drainage by catheter (eg, abscess, hematoma, seroma, lymphocele, cyst), soft tissue (eg, extremity, abdominal wall, neck), percutaneous	New	3.00	3.00	No
17000	Destruction (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement),	0.65	0.61	0.61	No

HCPCS Code	Long Descriptor	CY 2013 Work RVU	AMA RUC/ HCPAC Recommended Work RVU	CY 2014 Work RVU	CMS Time Refinement
	premalignant lesions (eg, actinic keratoses); first lesion				
17003	Destruction (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), premalignant lesions (eg, actinic keratoses); second through 14 lesions, each (list separately in addition to code for first lesion)	0.07	0.04	0.04	No
17004	Destruction (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), premalignant lesions (eg, actinic keratoses), 15 or more lesions	1.85	1.37	1.37	No
17311	Mohs micrographic technique, including removal of all gross tumor, surgical excision of tissue specimens, mapping, color coding of specimens, microscopic examination of specimens by the surgeon, and histopathologic preparation including routine stain(s) (eg, hematoxylin and eosin, toluidine blue), head, neck, hands, feet, genitalia, or any location with surgery directly involving muscle, cartilage, bone, tendon, major nerves, or vessels; first stage, up to 5 tissue blocks	6.20	6.20	6.20	No
17312	Mohs micrographic technique, including removal of all gross tumor, surgical excision of tissue specimens, mapping, color coding of specimens, microscopic examination of specimens by the surgeon, and histopathologic preparation including routine stain(s) (eg, hematoxylin and eosin, toluidine blue), head, neck, hands, feet, genitalia, or any location with surgery directly involving muscle, cartilage, bone, tendon, major nerves, or vessels; each additional stage after the first stage, up to 5 tissue blocks (list separately in addition to code for primary procedure)	3.30	3.30	3.30	No
17313	Mohs micrographic technique, including removal of all gross tumor, surgical	5.56	5.56	5.56	No

HCPCS Code	Long Descriptor	CY 2013 Work RVU	AMA RUC/ HCPAC Recommended Work RVU	CY 2014 Work RVU	CMS Time Refinement
	excision of tissue specimens, mapping, color coding of specimens, microscopic examination of specimens by the surgeon, and histopathologic preparation including routine stain(s) (eg, hematoxylin and eosin, toluidine blue), of the trunk, arms, or legs; first stage, up to 5 tissue blocks				
17314	Mohs micrographic technique, including removal of all gross tumor, surgical excision of tissue specimens, mapping, color coding of specimens, microscopic examination of specimens by the surgeon, and histopathologic preparation including routine stain(s) (eg, hematoxylin and eosin, toluidine blue), of the trunk, arms, or legs; each additional stage after the first stage, up to 5 tissue blocks (list separately in addition to code for primary procedure)	3.06	3.06	3.06	No
17315	Mohs micrographic technique, including removal of all gross tumor, surgical excision of tissue specimens, mapping, color coding of specimens, microscopic examination of specimens by the surgeon, and histopathologic preparation including routine stain(s) (eg, hematoxylin and eosin, toluidine blue), each additional block after the first 5 tissue blocks, any stage (list separately in addition to code for primary procedure)	0.87	0.87	0.87	No
19081	Biopsy, breast, with placement of breast localization device(s) (eg, clip, metallic pellet), when performed, and imaging of the biopsy specimen, when performed, percutaneous; first lesion, including stereotactic guidance	New	3.29	3.29	No
19082	Biopsy, breast, with placement of breast localization device(s) (eg, clip, metallic pellet), when performed, and imaging of the biopsy specimen, when performed, percutaneous; each additional lesion, including stereotactic guidance (list separately in addition to code for primary	New	1.65	1.65	No

HCPCS Code	Long Descriptor	CY 2013 Work RVU	AMA RUC/ HCPAC Recommended Work RVU	CY 2014 Work RVU	CMS Time Refinement
	procedure)				
19083	Biopsy, breast, with placement of breast localization device(s) (eg, clip, metallic pellet), when performed, and imaging of the biopsy specimen, when performed, percutaneous; first lesion, including ultrasound guidance	New	3.10	3.10	No
19084	Biopsy, breast, with placement of breast localization device(s) (eg, clip, metallic pellet), when performed, and imaging of the biopsy specimen, when performed, percutaneous; each additional lesion, including ultrasound guidance (list separately in addition to code for primary procedure)	New	1.55	1.55	No
19085	Biopsy, breast, with placement of breast localization device(s) (eg, clip, metallic pellet), when performed, and imaging of the biopsy specimen, when performed, percutaneous; first lesion, including magnetic resonance guidance	New	3.64	3.64	No
19086	Biopsy, breast, with placement of breast localization device(s) (eg, clip, metallic pellet), when performed, and imaging of the biopsy specimen, when performed, percutaneous; each additional lesion, including magnetic resonance guidance (list separately in addition to code for primary procedure)	New	1.82	1.82	No
19281	Placement of breast localization device(s) (eg, clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; first lesion, including mammographic guidance	New	2.00	2.00	No
19282	Placement of breast localization device(s) (eg, clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; each additional lesion, including mammographic guidance (list separately in addition to code for primary procedure)	New	1.00	1.00	No
19283	Placement of breast localization device(s) (eg, clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; first	New	2.00	2.00	No

HCPCS Code	Long Descriptor	CY 2013 Work RVU	AMA RUC/ HCPAC Recommended Work RVU	CY 2014 Work RVU	CMS Time Refinement
	lesion, including stereotactic guidance				
19284	Placement of breast localization device(s) (eg, clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; each additional lesion, including stereotactic guidance (list separately in addition to code for primary procedure)	New	1.00	1.00	No
19285	Placement of breast localization device(s) (eg, clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; first lesion, including ultrasound guidance	New	1.70	1.70	No
19286	Placement of breast localization device(s) (eg, clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; each additional lesion, including ultrasound guidance (list separately in addition to code for primary procedure)	New	0.85	0.85	Yes
19287	Placement of breast localization device(s) (eg clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; first lesion, including magnetic resonance guidance	New	3.02	2.55	No
19288	Placement of breast localization device(s) (eg clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; each additional lesion, including magnetic resonance guidance (list separately in addition to code for primary procedure)	New	1.51	1.28	No
23333	Removal of foreign body, shoulder; deep (subfascial or intramuscular)	New	6.00	6.00	No
23334	Removal of prosthesis, includes debridement and synovectomy when performed; humeral or glenoid component	New	18.89	15.50	No
23335	Removal of prosthesis, includes debridement and synovectomy when performed; humeral and glenoid components (eg, total shoulder)	New	22.13	19.00	No
24164	Removal of prosthesis, includes debridement and synovectomy when performed; radial head	6.43	10.00	10.00	No

HCPCS Code	Long Descriptor	CY 2013 Work RVU	AMA RUC/ HCPAC Recommended Work RVU	CY 2014 Work RVU	CMS Time Refinement
27130	Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft or allograft	21.79	19.60	20.72	Yes
27236	Open treatment of femoral fracture, proximal end, neck, internal fixation or prosthetic replacement	17.61	17.61	17.61	Yes
27446	Arthroplasty, knee, condyle and plateau; medial or lateral compartment	16.38	17.48	17.48	No
27447	Arthroplasty, knee, condyle and plateau; medial and lateral compartments with or without patella resurfacing (total knee arthroplasty)	23.25	19.60	20.72	Yes
31237	Nasal/sinus endoscopy, surgical; with biopsy, polypectomy or debridement (separate procedure)	2.98	2.60	2.60	No
31238	Nasal/sinus endoscopy, surgical; with control of nasal hemorrhage	3.26	2.74	2.74	No
31239	Nasal/sinus endoscopy, surgical; with dacryocystorhinostomy	9.33	9.04	9.04	No
31240	Nasal/sinus endoscopy, surgical; with concha bullosa resection	2.61	2.61	2.61	No
33282	Implantation of patient-activated cardiac event recorder	4.80	3.50	3.50	No
33284	Removal of an implantable, patient- activated cardiac event recorder	3.14	3.00	3.00	No
33366	Transcatheter aortic valve replacement (tavr/tavi) with prosthetic valve; transapical exposure (eg, left thoracotomy)	New	40.00	35.88	No
34841	Endovascular repair of visceral aorta (eg, aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) by deployment of a fenestrated visceral aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including one visceral artery endoprosthesis (superior mesenteric,	New	C	С	N/A

HCPCS Code	Long Descriptor	CY 2013 Work RVU	AMA RUC/ HCPAC Recommended Work RVU	CY 2014 Work RVU	CMS Time Refinement
	celiac or renal artery)				
34842	Endovascular repair of visceral aorta (eg, aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) by deployment of a fenestrated visceral aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including two visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])	New	С	С	N/A
34843	Endovascular repair of visceral aorta (eg, aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) by deployment of a fenestrated visceral aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including three visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])	New	C	С	N/A
34844	Endovascular repair of visceral aorta (eg, aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) by deployment of a fenestrated visceral aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including four or more visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])	New	C	C	N/A

HCPCS Code	Long Descriptor	CY 2013 Work RVU	AMA RUC/ HCPAC Recommended Work RVU	CY 2014 Work RVU	CMS Time Refinement
34845	Endovascular repair of visceral aorta and infrarenal abdominal aorta (eg, aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) with a fenestrated visceral aortic endograft and concomitant unibody or modular infrarenal aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including one visceral artery endoprosthesis (superior mesenteric, celiac or renal artery)	New	С	C	N/A
34846	Endovascular repair of visceral aorta and infrarenal abdominal aorta (eg, aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) with a fenestrated visceral aortic endograft and concomitant unibody or modular infrarenal aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including two visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])	New	С	С	N/A
34847	Endovascular repair of visceral aorta and infrarenal abdominal aorta (eg, aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) with a fenestrated visceral aortic endograft and concomitant unibody or modular infrarenal aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including three visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])	New	C	С	N/A
34848	Endovascular repair of visceral aorta and infrarenal abdominal aorta (eg, aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) with a fenestrated visceral	New	С	С	N/A

HCPCS Code	Long Descriptor	CY 2013 Work RVU	AMA RUC/ HCPAC Recommended Work RVU	CY 2014 Work RVU	CMS Time Refinement
	aortic endograft and concomitant unibody or modular infrarenal aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including four or more visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])				
35301	Thromboendarterectomy, including patch graft, if performed; carotid, vertebral, subclavian, by neck incision	19.61	21.16	21.16	No
36245	Selective catheter placement, arterial system; each first order abdominal, pelvic, or lower extremity artery branch, within a vascular family	4.67	4.90	4.90	No
37217	Transcatheter placement of an intravascular stent(s), intrathoracic common carotid artery or innominate artery by retrograde treatment, via open ipsilateral cervical carotid artery exposure, including angioplasty, when performed, and radiological supervision and interpretation	New	22.00	20.38	No
37236	Transcatheter placement of an intravascular stent(s) (except lower extremity, cervical carotid, extracranial vertebral or intrathoracic carotid, intracranial, or coronary), open or percutaneous, including radiological supervision and interpretation and including all angioplasty within the same vessel, when performed; initial artery	New	9.00	9.00	No
37237	Transcatheter placement of an intravascular stent(s) (except lower extremity, cervical carotid, extracranial vertebral or intrathoracic carotid, intracranial, or coronary), open or percutaneous, including radiological supervision and interpretation and including all angioplasty within the same vessel, when performed; each additional artery (list separately in addition to code for primary procedure)	New	4.25	4.25	No

HCPCS Code	Long Descriptor	CY 2013 Work RVU	AMA RUC/ HCPAC Recommended Work RVU	CY 2014 Work RVU	CMS Time Refinement
37238	Transcatheter placement of an intravascular stent(s), open or percutaneous, including radiological supervision and interpretation and including angioplasty within the same vessel, when performed; initial vein	New	6.29	6.29	No
37239	Transcatheter placement of an intravascular stent(s), open or percutaneous, including radiological supervision and interpretation and including angioplasty within the same vessel, when performed; each additional vein (list separately in addition to code for primary procedure)	New	3.34	2.97	No
37241	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; venous, other than hemorrhage (eg, congenital or acquired venous malformations, venous and capillary hemangiomas, varices, varicoceles)	New	9.00	9.00	No
37242	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; arterial, other than hemorrhage or tumor (eg, congenital or acquired arterial malformations, arteriovenous malformations, arteriovenous fistulas, aneurysms, pseudoaneurysms)	New	11.98	10.05	No
37243	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for tumors, organ ischemia, or infarction	New	14.00	11.99	No
37244	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention;	New	14.00	14.00	No

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	for arterial or venous hemorrhage or lymphatic extravasation				
43191	Esophagoscopy, rigid, transoral; diagnostic, including collection of specimen(s) by brushing or washing when performed (separate procedure)	New	2.78	2.00	No
43192	Esophagoscopy, rigid, transoral; with directed submucosal injection(s), any substance	New	3.21	2.45	No
43193	Esophagoscopy, rigid, transoral; with biopsy, single or multiple	New	3.36	3.00	No
43194	Esophagoscopy, rigid, transoral; with removal of foreign body	New	3.99	3.00	No
43195	Esophagoscopy, rigid, transoral; with balloon dilation (less than 30 mm diameter)	New	3.21	3.00	No
43196	Esophagoscopy, rigid, transoral; with insertion of guide wire followed by dilation over guide wire	New	3.36	3.30	No
43197	Esophagoscopy, flexible, transnasal; diagnostic, includes collection of specimen(s) by brushing or washing when performed (separate procedure)	New	1.59	1.48	Yes
43198	Esophagoscopy, flexible, transnasal; with biopsy, single or multiple	New	1.89	1.78	Yes
43200	Esophagoscopy, flexible, transoral; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)	1.59	1.59	1.50	No
43201	Esophagoscopy, flexible, transoral; with directed submucosal injection(s), any substance	2.09	1.90	1.80	No
43202	Esophagoscopy, flexible, transoral; with biopsy, single or multiple	1.89	1.89	1.80	No
43204	Esophagoscopy, flexible, transoral; with injection sclerosis of esophageal varices	3.76	2.89	2.40	No
43205	Esophagoscopy, flexible, transoral; with band ligation of esophageal varices	3.78	3.00	2.51	No
43211	Esophagoscopy, flexible, transoral; with endoscopic mucosal resection	New	4.58	4.21	No
43212	Esophagoscopy, flexible, transoral; with placement of endoscopic stent (includes pre- and post-dilation and guide wire	New	3.73	3.38	No

HCPCS Code	Long Descriptor	CY 2013 Work RVU	AMA RUC/ HCPAC Recommended Work RVU	CY 2014 Work RVU	CMS Time Refinement
	passage, when performed)				
43213	Esophagoscopy, flexible, transoral; with dilation of esophagus, by balloon or dilator, retrograde (includes fluoroscopic guidance, when performed)	New	5.00	4.73	No
43214	Esophagoscopy, flexible, transoral; with dilation of esophagus with balloon (30 mm diameter or larger) (includes fluoroscopic guidance, when performed)	New	3.78	3.38	No
43215	Esophagoscopy, flexible, transoral; with removal of foreign body	2.60	2.60	2.51	No
43216	Esophagoscopy, flexible, transoral; with removal of tumor(s), polyp(s), or other lesion(s) by hot biopsy forceps or bipolar cautery	2.40	2.40	2.40	No
43217	Esophagoscopy, flexible, transoral; with removal of tumor(s), polyp(s), or other lesion(s) by snare technique	2.90	2.90	2.90	No
43220	Esophagoscopy, flexible, transoral; with transendoscopic balloon dilation (less than 30 mm diameter)	2.10	2.10	2.10	No
43226	Esophagoscopy, flexible, transoral; with insertion of guide wire followed by passage of dilator(s) over guide wire	2.34	2.34	2.34	No
43227	Esophagoscopy, flexible, transoral; with control of bleeding, any method	3.59	3.26	2.99	No
43229	Esophagoscopy, flexible, transoral; with ablation of tumor(s), polyp(s), or other lesion(s) (includes pre- and post-dilation and guide wire passage, when performed)	New	3.72	3.54	No
43231	Esophagoscopy, flexible, transoral; with endoscopic ultrasound examination	3.19	3.19	2.90	No
43232	Esophagoscopy, flexible, transoral; with transendoscopic ultrasound-guided intramural or transmural fine needle aspiration/biopsy(s)	4.47	3.83	3.54	No
43233	Esophagogastroduodenoscopy, flexible, transoral; with dilation of esophagus with balloon (30 mm diameter or larger) (includes fluoroscopic guidance, when performed)	New	4.45	4.05	No
43235	Esophagogastroduodenoscopy, flexible,	2.39	2.26	2.17	No

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	transoral; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)				
43236	Esophagogastroduodenoscopy, flexible, transoral; with directed submucosal injection(s), any substance	2.92	2.57	2.47	No
43237	Esophagogastroduodenoscopy, flexible, transoral; with endoscopic ultrasound examination limited to the esophagus, stomach or duodenum, and adjacent structures	3.98	3.85	3.57	No
43238	Esophagogastroduodenoscopy, flexible, transoral; with transendoscopic ultrasound-guided intramural or transmural fine needle aspiration/biopsy(s), esophagus (includes endoscopic ultrasound examination limited to the esophagus, stomach or duodenum, and adjacent structures)	5.02	4.50	4.11	No
43239	Esophagogastroduodenoscopy, flexible, transoral; with biopsy, single or multiple	2.87	2.56	2.47	No
43240	Esophagogastroduodenoscopy, flexible, transoral; with transmural drainage of pseudocyst (includes placement of transmural drainage catheter[s]/stent[s], when performed, and endoscopic ultrasound, when performed)	6.85	7.25	7.25	No
43241	Esophagogastroduodenoscopy, flexible, transoral; with insertion of intraluminal tube or catheter	2.59	2.59	2.59	No
43242	Esophagogastroduodenoscopy, flexible, transoral; with transendoscopic ultrasound-guided intramural or transmural fine needle aspiration/biopsy(s) (includes endoscopic ultrasound examination of the esophagus, stomach, and either the duodenum or a surgically altered stomach where the jejunum is examined distal to the anastomosis)	7.30	5.39	4.68	No
43243	Esophagogastroduodenoscopy, flexible, transoral; with injection sclerosis of esophageal/gastric varices	4.56	4.37	4.37	No
43244	Esophagogastroduodenoscopy, flexible,	5.04	4.50	4.50	No

HCPCS Code	Long Descriptor	CY 2013 Work RVU	AMA RUC/ HCPAC Recommended Work RVU	CY 2014 Work RVU	CMS Time Refinement
	transoral; with band ligation of				
	esophageal/gastric varices				
43245	Esophagogastroduodenoscopy, flexible, transoral; with dilation of gastric/duodenal stricture(s) (eg, balloon, bougie)	3.18	3.18	3.18	No
43246	Esophagogastroduodenoscopy, flexible, transoral; with directed placement of percutaneous gastrostomy tube	4.32	4.32	3.66	No
43247	Esophagogastroduodenoscopy, flexible, transoral; with removal of foreign body	3.38	3.27	3.18	No
43248	Esophagogastroduodenoscopy, flexible, transoral; with insertion of guide wire followed by passage of dilator(s) through esophagus over guide wire	3.15	3.01	3.01	No
43249	Esophagogastroduodenoscopy, flexible, transoral; with transendoscopic balloon dilation of esophagus (less than 30 mm diameter)	2.90	2.77	2.77	No
43250	Esophagogastroduodenoscopy, flexible, transoral; with removal of tumor(s), polyp(s), or other lesion(s) by hot biopsy forceps or bipolar cautery	3.20	3.07	3.07	No
43251	Esophagogastroduodenoscopy, flexible, transoral; with removal of tumor(s), polyp(s), or other lesion(s) by snare technique	3.69	3.57	3.57	No
43253	Esophagogastroduodenoscopy, flexible, transoral; with transendoscopic ultrasound-guided transmural injection of diagnostic or therapeutic substance(s) (eg, anesthetic, neurolytic agent) or fiducial marker(s) (includes endoscopic ultrasound examination of the esophagus, stomach, and either the duodenum or a surgically altered stomach where the jejunum is examined distal to the anastomosis)	New	5.39	4.68	No
43254	Esophagogastroduodenoscopy, flexible, transoral; with endoscopic mucosal resection	New	5.25	4.88	No
43255	Esophagogastroduodenoscopy, flexible, transoral; with control of bleeding, any method	4.81	4.20	3.66	No

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43257	Esophagogastroduodenoscopy, flexible, transoral; with delivery of thermal energy to the muscle of lower esophageal sphincter and/or gastric cardia, for treatment of gastroesophageal reflux disease	5.50	4.25	4.11	No
43259	Esophagogastroduodenoscopy, flexible, transoral; with endoscopic ultrasound examination, including the esophagus, stomach, and either the duodenum or a surgically altered stomach where the jejunum is examined distal to the anastomosis	5.19	4.74	4.14	No
43260	Endoscopic retrograde cholangiopancreatography (ercp); diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)	5.95	5.95	5.95	No
43261	Endoscopic retrograde cholangiopancreatography (ercp); with biopsy, single or multiple	6.26	6.25	6.25	No
43262	Endoscopic retrograde cholangiopancreatography (ercp); with sphincterotomy/papillotomy	7.38	6.60	6.60	No
43263	Endoscopic retrograde cholangiopancreatography (ercp); with pressure measurement of sphincter of oddi	7.28	7.28	6.60	No
43264	Endoscopic retrograde cholangiopancreatography (ercp); with removal of calculi/debris from biliary/pancreatic duct(s)	8.89	6.73	6.73	No
43265	Endoscopic retrograde cholangiopancreatography (ercp); with destruction of calculi, any method (eg, mechanical, electrohydraulic, lithotripsy)	10.00	8.03	8.03	No
43266	Esophagogastroduodenoscopy, flexible, transoral; with placement of endoscopic stent (includes pre- and post-dilation and guide wire passage, when performed)	New	4.40	4.05	No

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43270	Esophagogastroduodenoscopy, flexible, transoral; with ablation of tumor(s), polyp(s), or other lesion(s) (includes preand post-dilation and guide wire passage, when performed)	New	4.39	4.21	No
43273	Endoscopic cannulation of papilla with direct visualization of pancreatic/common bile duct(s) (list separately in addition to code(s) for primary procedure)	2.24	2.24	2.24	No
43274	Endoscopic retrograde cholangiopancreatography (ercp); with placement of endoscopic stent into biliary or pancreatic duct, including pre- and post-dilation and guide wire passage, when performed, including sphincterotomy, when performed, each stent	New	8.74	8.48	No
43275	Endoscopic retrograde cholangiopancreatography (ercp); with removal of foreign body(s) or stent(s) from biliary/pancreatic duct(s)	New	6.96	6.96	No
43276	Endoscopic retrograde cholangiopancreatography (ercp); with removal and exchange of stent(s), biliary or pancreatic duct, including pre- and post-dilation and guide wire passage, when performed, including sphincterotomy, when performed, each stent exchanged	New	9.10	8.84	No
43277	Endoscopic retrograde cholangiopancreatography (ercp); with trans-endoscopic balloon dilation of biliary/pancreatic duct(s) or of ampulla (sphincteroplasty), including sphincterotomy, when performed, each duct	New	7.11	7.00	No
43278	Endoscopic retrograde cholangiopancreatography (ercp); with ablation of tumor(s), polyp(s), or other lesion(s), including pre- and post-dilation and guide wire passage, when performed	New	8.08	7.99	No
43450	Dilation of esophagus, by unguided sound or bougie, single or multiple	1.38	1.38	1.38	No

HCPCS Code	Long Descriptor	CY 2013 Work RVU	AMA RUC/ HCPAC Recommended Work RVU	CY 2014 Work RVU	CMS Time Refinement
	passes				
43453	Dilation of esophagus, over guide wire	1.51	1.51	1.51	No
49405	Image-guided fluid collection drainage by catheter (eg, abscess, hematoma, seroma, lymphocele, cyst); visceral (eg, kidney, liver, spleen, lung/mediastinum), percutaneous	New	4.25	4.25	No
49406	Image-guided fluid collection drainage by catheter (eg, abscess, hematoma, seroma, lymphocele, cyst); peritoneal or retroperitoneal, percutaneous	New	4.25	4.25	No
49407	Image-guided fluid collection drainage by catheter (eg, abscess, hematoma, seroma, lymphocele, cyst); peritoneal or retroperitoneal, transvaginal or transrectal	New	4.50	4.50	No
50360	Renal allotransplantation, implantation of graft; without recipient nephrectomy	40.90	40.90	39.88	No
52332	Cystourethroscopy, with insertion of indwelling ureteral stent (eg, gibbons or double-j type)	2.82	2.82	2.82	No
52356	Cystourethroscopy, with ureteroscopy and/or pyeloscopy; with lithotripsy including insertion of indwelling ureteral stent (eg, gibbons or double-j type)	New	8.00	8.00	No
62310	Injection(s), of diagnostic or therapeutic substance(s) (including anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, includes contrast for localization when performed, epidural or subarachnoid; cervical or thoracic	1.91	1.68	1.18	No
62311	Injection(s), of diagnostic or therapeutic substance(s) (including anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, includes contrast for localization when performed, epidural or subarachnoid; lumbar or sacral (caudal)	1.54	1.54	1.17	No
62318	Injection(s), including indwelling catheter placement, continuous infusion or intermittent bolus, of diagnostic or therapeutic substance(s) (including	2.04	2.04	1.54	No

HCPCS Code	Long Descriptor	CY 2013 Work RVU	AMA RUC/ HCPAC Recommended Work RVU	CY 2014 Work RVU	CMS Time Refinement
	anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, includes contrast for localization when performed, epidural or subarachnoid; cervical or thoracic				
62319	Injection(s), including indwelling catheter placement, continuous infusion or intermittent bolus, of diagnostic or therapeutic substance(s) (including anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, includes contrast for localization when performed, epidural or subarachnoid; lumbar or sacral (caudal)	1.87	1.87	1.50	No
63047	Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [eg, spinal or lateral recess stenosis]), single vertebral segment; lumbar	15.37	15.37	15.37	No
63048	Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [eg, spinal or lateral recess stenosis]), single vertebral segment; each additional segment, cervical, thoracic, or lumbar (list separately in addition to code for primary procedure)	3.47	3.47	3.47	No
64616	Chemodenervation of muscle(s); neck muscle(s), excluding muscles of the larynx, unilateral (eg, for cervical dystonia, spasmodic torticollis)	New	1.79	1.53	No
64617	Chemodenervation of muscle(s); larynx, unilateral, percutaneous (eg, for spasmodic dysphonia), includes guidance by needle electromyography, when performed	New	2.06	1.90	No
64642	Chemodenervation of one extremity; 1-4 muscle(s)	New	1.65	1.65	No
64643	Chemodenervation of one extremity; each additional extremity, 1-4 muscle(s) (list separately in addition to code for primary procedure)	New	1.32	1.22	No

HCPCS Code	Long Descriptor	CY 2013 Work RVU	AMA RUC/ HCPAC Recommended Work RVU	CY 2014 Work RVU	CMS Time Refinement
64644	Chemodenervation of one extremity; 5 or more muscle(s)	New	1.82	1.82	No
64645	Chemodenervation of one extremity; each additional extremity, 5 or more muscle(s) (list separately in addition to code for primary procedure)	New	1.52	1.39	No
64646	Chemodenervation of trunk muscle(s); 1-5 muscle(s)	New	1.80	1.80	No
64647	Chemodenervation of trunk muscle(s); 6 or more muscle(s)	New	2.11	2.11	No
66183	Insertion of anterior segment aqueous drainage device, without extraocular reservoir, external approach	New	13.20	13.20	No
67914	Repair of ectropion; suture	3.75	3.75	3.75	No
67915	Repair of ectropion; thermocauterization	3.26	2.03	2.03	No
67916	Repair of ectropion; excision tarsal wedge	5.48	5.48	5.48	No
67917	Repair of ectropion; extensive (eg, tarsal strip operations)	6.19	5.93	5.93	No
67921	Repair of entropion; suture	3.47	3.47	3.47	No
67922	Repair of entropion; thermocauterization	3.14	2.03	2.03	No
67923	Repair of entropion; excision tarsal wedge	6.05	5.48	5.48	No
67924	Repair of entropion; extensive (eg, tarsal strip or capsulopalpebral fascia repairs operation)	5.93	5.93	5.93	No
69210	Removal impacted cerumen requiring instrumentation, unilateral	0.61	0.58	0.61	No
70450	Computed tomography, head or brain; without contrast material	0.85	0.85	0.85	No
70460	Computed tomography, head or brain; with contrast material(s)	1.13	1.13	1.13	No
70551	Magnetic resonance (eg, proton) imaging, brain (including brain stem); without contrast material	1.48	1.48	1.48	No
70552	Magnetic resonance (eg, proton) imaging, brain (including brain stem); with contrast material(s)	1.78	1.78	1.78	No
70553	Magnetic resonance (eg, proton) imaging, brain (including brain stem); without contrast material, followed by contrast material(s) and further sequences	2.36	2.36	2.29	No
72141	Magnetic resonance (eg, proton) imaging, spinal canal and contents, cervical;	1.60	1.48	1.48	No

HCPCS Code	Long Descriptor	CY 2013 Work RVU	AMA RUC/ HCPAC Recommended Work RVU	CY 2014 Work RVU	CMS Time Refinement
	without contrast material				
72142	Magnetic resonance (eg, proton) imaging, spinal canal and contents, cervical; with contrast material(s)	1.92	1.78	1.78	No
72146	Magnetic resonance (eg, proton) imaging, spinal canal and contents, thoracic; without contrast material	1.60	1.48	1.48	No
72147	Magnetic resonance (eg, proton) imaging, spinal canal and contents, thoracic; with contrast material(s)	1.92	1.78	1.78	No
72148	Magnetic resonance (eg, proton) imaging, spinal canal and contents, lumbar; without contrast material	1.48	1.48	1.48	No
72149	Magnetic resonance (eg, proton) imaging, spinal canal and contents, lumbar; with contrast material(s)	1.78	1.78	1.78	No
72156	Magnetic resonance (eg, proton) imaging, spinal canal and contents, without contrast material, followed by contrast material(s) and further sequences; cervical	2.57	2.29	2.29	No
72157	Magnetic resonance (eg, proton) imaging, spinal canal and contents, without contrast material, followed by contrast material(s) and further sequences; thoracic	2.57	2.29	2.29	No
72158	Magnetic resonance (eg, proton) imaging, spinal canal and contents, without contrast material, followed by contrast material(s) and further sequences; lumbar	2.36	2.29	2.29	No
77280	Therapeutic radiology simulation-aided field setting; simple	0.70	0.70	0.70	No
77285	Therapeutic radiology simulation-aided field setting; intermediate	1.05	1.05	1.05	No
77290	Therapeutic radiology simulation-aided field setting; complex	1.56	1.56	1.56	No
77293	Respiratory motion management simulation (list separately in addition to code for primary procedure)	New	2.00	2.00	No
77295	3-dimensional radiotherapy plan, including dose-volume histograms	4.56	4.29	4.29	No
81161	Dmd (dystrophin) (eg, duchenne/becker muscular dystrophy) deletion analysis, and duplication analysis, if performed	New	1.85	X	N/A

HCPCS Code	Long Descriptor	CY 2013 Work RVU	AMA RUC/ HCPAC Recommended Work RVU	CY 2014 Work RVU	CMS Time Refinement
88112	Cytopathology, selective cellular enhancement technique with interpretation (eg, liquid based slide preparation method), except cervical or vaginal	1.18	0.56	0.56	No
88342	Immunohistochemistry or immunocytochemistry, each separately identifiable antibody per block, cytologic preparation, or hematologic smear; first separately identifiable antibody per slide	0.85	0.60	I	N/A
88343	Immunohistochemistry or immunocytochemistry, each separately identifiable antibody per block, cytologic preparation, or hematologic smear; each additional separately identifiable antibody per slide (list separately in addition to code for primary procedure)	New	0.24	I	N/A
92521	Evaluation of speech fluency (eg, stuttering, cluttering)	New	1.75	1.75	No
92522	Evaluation of speech sound production (eg, articulation, phonological process, apraxia, dysarthria);	New	1.50	1.50	No
92523	Evaluation of speech sound production (eg, articulation, phonological process, apraxia, dysarthria); with evaluation of language comprehension and expression (eg, receptive and expressive language)	New	3.36	3.00	No
92524	Behavioral and qualitative analysis of voice and resonance	New	1.75	1.50	No
93000	Electrocardiogram, routine ecg with at least 12 leads; with interpretation and report	0.17	0.17	0.17	No
93010	Electrocardiogram, routine ecg with at least 12 leads; interpretation and report only	0.17	0.17	0.17	No
93582	Percutaneous transcatheter closure of patent ductus arteriosus	New	14.00	12.56	No
93583	Percutaneous transcatheter septal reduction therapy (eg, alcohol septal ablation) including temporary pacemaker insertion when performed	New	14.00	14.00	No
93880	Duplex scan of extracranial arteries; complete bilateral study	0.60	0.80	0.60	No

HCPCS Code	Long Descriptor	CY 2013 Work RVU	AMA RUC/ HCPAC Recommended Work RVU	CY 2014 Work RVU	CMS Time Refinement
93882	Duplex scan of extracranial arteries; unilateral or limited study	0.40	0.50	0.40	No
95816	Electroencephalogram (eeg); including recording awake and drowsy	1.08	1.08	1.08	No
95819	Electroencephalogram (eeg); including recording awake and asleep	1.08	1.08	1.08	No
95822	Electroencephalogram (eeg); recording in coma or sleep only	1.08	1.08	1.08	No
96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour	0.21	0.21	0.21	No
96366	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour (list separately in addition to code for primary procedure)	0.18	0.18	0.18	No
96367	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); additional sequential infusion of a new drug/substance, up to 1 hour (list separately in addition to code for primary procedure)	0.19	0.19	0.19	No
96368	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); concurrent infusion (list separately in addition to code for primary procedure)	0.17	0.17	0.17	No
96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug	0.28	0.28	0.28	No
96415	Chemotherapy administration, intravenous infusion technique; each additional hour (list separately in addition to code for primary procedure)	0.19	0.19	0.19	No
96417	Chemotherapy administration, intravenous infusion technique; each additional sequential infusion (different substance/drug), up to 1 hour (list separately in addition to code for primary procedure)	0.21	0.21	0.21	No
97610	Low frequency, non-contact, non-thermal ultrasound, including topical application(s), when performed, wound assessment, and instruction(s) for	New	С	С	N/A

HCPCS Code	Long Descriptor	CY 2013 Work RVU	AMA RUC/ HCPAC Recommended Work RVU	CY 2014 Work RVU	CMS Time Refinement
	ongoing care, per day				
98940	Chiropractic manipulative treatment (cmt); spinal, 1-2 regions	0.45	0.46	0.46	No
98941	Chiropractic manipulative treatment (cmt); spinal, 3-4 regions	0.65	0.71	0.71	No
98942	Chiropractic manipulative treatment (cmt); spinal, 5 regions	0.87	0.96	0.96	No
99446	Interprofessional telephone/internet assessment and management service provided by a consultative physician including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional; 5-10 minutes of medical consultative discussion and review	New	0.35	В	No
99447	Interprofessional telephone/internet assessment and management service provided by a consultative physician including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional; 11-20 minutes of medical consultative discussion and review	New	0.70	В	No
99448	Interprofessional telephone/internet assessment and management service provided by a consultative physician including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional; 21-30 minutes of medical consultative discussion and review	New	1.05	В	No
99449	Interprofessional telephone/internet assessment and management service provided by a consultative physician including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional; 31 minutes or more of medical consultative discussion and review	New	1.40	В	No
99481	Total body systemic hypothermia in a critically ill neonate per day (list separately in addition to code for primary	New	С	С	N/A

HCPCS Code	Long Descriptor	CY 2013 Work RVU	AMA RUC/ HCPAC Recommended Work RVU	CY 2014 Work RVU	CMS Time Refinement
	procedure)				
99482	Selective head hypothermia in a critically ill neonate per day (list separately in addition to code for primary procedure)	New	С	С	N/A
G0461	Immunohistochemistry or immunocytochemistry, per specimen; first separately identifiable antibody	New	N/A	0.60	No
G0462	Immunohistochemistry or immunocytochemistry, per specimen; each additional separately identifiable antibody (List separately in addition to code for primary procedure).	New	N/A	0.24	No

As previously discussed in section III.E.2 of this final rule with comment period, each year, the AMA RUC and HCPAC, along with other public commenters, provide us with recommendations regarding physician work values for new, revised, and potentially misvalued CPT codes. This section discusses codes for which the interim final work RVU or time values assigned for CY 2014 vary from those recommended by the AMA RUC. It also discusses work RVU and time values for new and revised HCPCS G-codes.

i. Code Specific Issues

(1) Breast Biopsy (CPT Codes 19081, 19082, 19083, 19084, 19085, 19086, 19281, 19282, 19283, 19284, 19285, 19286, 19287, and 19288)

The AMA RUC identified several breast intervention codes as potentially misvalued using the codes reported together 75 percent or more screen as potentially misvalued. For CY 2014, the CPT Editorial Panel created 14 new codes, CPT codes 19081through 19288, to describe breast biopsy and placement of breast localization devices.

We are establishing the AMA RUC-recommended values as CY 2014 interim final values for all of the breast biopsy codes with the exception of CPT code 19287 and its add-on CPT code, 19288. We believe that the work RVU recommended by the AMA RUC for CPT code 19287 would create a rank

order anomaly with other codes in the family. To avoid this anomaly, we are assigning a CY 2014 interim final work RVU of 2.55, which is between the 25th percentile and the median work RVU in the survey. In determining how to value this service, we examined the work RVU relationship among the breast biopsy codes as established by the AMA RUC and believed those to be correct. We used those relationships to establish the value for CPT code 19287. We believe that using this work value creates the appropriate relativity with other codes in the family.

To value CPT code 19288, we followed the same procedure used by the AMA RUC in making its recommendation for the add-on codes, which was to value add-on services at 50 percent of the applicable base code value, resulting in a work RVU of 1.28 for CPT code 19288.

We received public input suggesting that when one of these procedures is performed without mammography guidance, mammography is commonly performed afterwards to confirm appropriate placement. We seek public input as to whether or not post-procedure mammography is commonly furnished with breast biopsy and marker placement, and if so, whether the services should be bundled together.

Finally, we note that the physician intraservice time for CPT code 19286, which is an add-on code, is 19 minutes, which is higher than the 15 minutes of intraservice time for its base code, CPT code 19285. Therefore we are reducing the intraservice time for CPT code 19286 to the survey 25th percentile value of 14 minutes.

(2) Shoulder Prosthesis Removal (CPT Codes 23333, 23334, and 23335)

Three new codes, CPT codes 23333, 23334 and 23335, were created to replace CPT codes 23331 (removal of foreign body, shoulder; deep (eg, Neer hemiarthroplasty removal)) and 23332 (removal of foreign body, shoulder; complicated (eg, total shoulder)).

We are establishing a CY 2014 interim final work RVU of 6.00 for CPT code 23333, as recommended by the AMA RUC.

The AMA RUC recommended a work RVU of 18.89 for CPT code 23334 based on a crosswalk to the work value of CPT code 27269 (Open treatment of femoral fracture, proximal end, head, includes

internal fixation, when performed). The code currently reported for this service, CPT code 23331, has a work RVU of 7.63. Recognizing that more physician time is involved with CPT code 23334 than CPT code 23331 and that the technique for removal of prosthesis may have changed since its last valuation, we still do not believe that the work has more than doubled for this service. Therefore, instead of assigning a work RVU of 18.89, we are assigning CPT 23334 a CY 2014 interim final work RVU of 15.50, based upon the 25th percentile of the survey. We believe this more appropriately reflects the work required to furnish this service.

Similarly, we believe that the 25th percentile of the survey also provides the appropriate work RVU for CPT code 23335. The AMA RUC recommended a work RVU of 22.13 based on a crosswalk to the CY 2013 interim final value of CPT code 23472 (Arthroplasty, glenohumeral joint; total shoulder (glenoid and proximal humeral replacement (eg, total shoulder))). CPT code 23332 is currently billed for the work of new CPT code 23335 and has a work RVU of 12.37. Although the physician time for CPT code 23335 has increased from that of the predecessor code, CPT code 22332, and the technique for removal of prosthesis may have changed, we do not believe that the work has almost doubled for this service. Therefore, we are assigning a work RVU of 19.00 based upon the 25th percentile work RVU in the survey. We believe this appropriately reflects the work required to perform this service.

CPT codes CY 27130, 27446 and 27447 were identified as potentially misvalued codes under the CMS high expenditure procedural code screen in the CY 2012 final rule with comment period. The AMA RUC reviewed the family of codes for hip and knee replacement (CPT codes 27130, 27236, 27446 and 27447) and provided us with recommendations for work RVUs and physician time for these services for CY 2014. We are establishing the AMA RUC-recommended values of 17.61 and 17.48 a CY 2014 interim final work RVUs for CPT codes 27236 and 27446, respectively.

For CPT codes 27130 and 27447, we are establishing work RVUs that vary from those recommended by the AMA RUC. In addition to the recommendation we received from the AMA RUC, we received alternative recommendations and input regarding appropriate values for codes within this

family from the relevant specialty societies. These societies raised several objections to the AMA RUC's recommended values, including the inconsistent data sources used for determining the time for this recommendation relative to its last recommendation in 2005, concerns regarding the thoroughness of the AMA RUC's review of the services, and questions regarding the appropriate number of visits estimated to be furnished within the global period for the codes.

We have examined the information presented by the specialty societies and the AMA RUC regarding these services and we share concerns raised by stakeholders regarding the appropriate valuation of these services, especially related to using the most accurate data source available for determining the intraservice time involved in furnishing PFS services. Specifically, there appears to be significant variation between the time values estimated through a survey versus those collected through specialty databases. However, we also note that the AMA RUC, in making its recommendation, acknowledged that there has been a change in the source for time estimates since these services were previously valued.

We note that one source of disagreement regarding the appropriate valuation of these services result from differing views as to the postoperative visits that typically occur in the global period for both of these procedures. The AMA RUC recommended including three inpatient postoperative visits (2 CPT code 99231 and one CPT code 99232), one discharge day management visit (99238), and three outpatient postoperative office visits (1 CPT code 99212 and 2 CPT code 99213) in the global periods for both CPT codes 27130 and 27447. The specialty societies agreed with the number of visits included in the AMA RUC recommendation, but contended that the visits were not assigned to the appropriate level.

Specifically, the specialty societies believe that the three inpatient postoperative visits should be 1 CPT code 99231 and 2 CPT code 99232. Similarly, the specialty societies indicated that the three outpatient postoperative visits should all be CPT code 99213. The visits recommended by the specialty societies would result in greater resources in the global period and thus higher work values.

The divergent recommendations from the specialty societies and the AMA RUC regarding the accuracy of the estimates of time for these services, including both the source of time estimates for the

procedure itself as well as the inpatient and outpatient visits included in the global periods for these codes, lead us to take a cautious approach in valuing these services.

We agree with the AMA RUC's recommendation to value CPT codes 27130 and 27447 equally so we are establishing the same CY 2014 interim final work RVUs for these two procedures. However, based upon the information that we have at this time, we believe it is also appropriate to modify the AMA RUC-recommended RVU to reflect the visits in the global period as recommended by the specialty societies. This change results in a 1.12 work RVU increase for the visits in the global period. We added the additional work to the AMA RUC-recommended work RVU of 19.60 for CPT codes 27130 and 27447, resulting in an interim final work RVU of 20.72 for both services.

To finalize values for these services for CY 2015, we seek public comment regarding not only the appropriate work RVUs for these services, but also the most appropriate reconciliation for the conflicting information regarding time values for these services as presented to us by the physician community. We are also interested in public comment on the use of specialty databases as compared to surveys for determining time values. We are especially interested in potential sources of objective data regarding procedure times and levels of visits furnished during the global periods for the services described by these codes.

(4) Transcatheter Aortic Valve Replacement (TAVR) (CPT Code 33366)

For the CY 2013 final rule with comment period, we reviewed and valued several codes within the transcatheter aortic valve replacement (TAVR) family including CPT Codes 33361 (transcatheter aortic valve replacement (tavr/tavi) with prosthetic valve; percutaneous femoral artery approach), 33362 (transcatheter aortic valve replacement (tavr/tavi) with prosthetic valve; open femoral artery approach), 33363 (transcatheter aortic valve replacement (tavr/tavi) with prosthetic valve; open axillary artery approach), 33364 (transcatheter aortic valve replacement (tavr/tavi) with prosthetic valve; open iliac artery approach) and 33365 (transcatheter aortic valve replacement (tavr/tavi) with prosthetic valve; transaortic approach (eg, median sternotomy, mediastinotomy)). For these codes, we finalized the CY

2013 interim final values for CY 2014 (see section II.E.2.a.ii.) For CY 2014, CPT created a new code in the TAVR family, CPT code 33366, (Treath replace agric value).

The AMA RUC has recommended the median survey value RVU of 40.00 for CPT Code 33366. After review, we believe that a work RVU of 35.88, which is between the survey's 25th percentile of 30.00 and the median of 40.00, accurately reflects the work associated with this service. The median intraservice time from the survey for CPT code 33365 is 180 minutes and for CPT code 33366 is 195. Using a ratio between the times for these procedures we determined the current work RVU of 33.12 for CPT code 33365 results in the work RVU of 35.88 for CPT code 33366. We believe that an RVU of 35.88 more appropriately reflects the work required to perform CPT code 33366 and maintains appropriate relativity among these five codes. We are establishing a CY 2014 interim final work RVU of 35.88 for CPT code 33366.

(5) Retrograde Treatment Open Carotid Stent (CPT Code 37217)

The CPT Editorial Panel created CPT Code 37217, effective January 1, 2014. The AMA RUC recommended a work RVU of 22.00, the median from the survey, and an intraservice time of 120 minutes.

The AMA RUC identified CPT Code 37215 (Transcatheter placement of intravascular stent(s), cervical carotid artery, percutaneous; with distal embolic protection), which has an RVU of 19.68, as the key reference code for CPT code 37217. For its recommendations, the AMA RUC also compared CPT code 37217 to CPT Code 35301 (thromboendarterectomy, including patch graft, if performed; carotid, vertebral, subclavian, by neck incision), which has a work RVU of 19.61, and CPT code 35606 (Bypass graft, with other than vein; carotid-subclavian), which has a work RVU of 22.46.

In our review, we used the same comparison codes for CPT code 37217 as the AMA RUC used in valuing CPT code 37217. To assess the work RVUs for CPT code 37217 relative to CPT code 35606, we compared the AMA RUC-recommended work RVUs after removing the inpatient and outpatient visits in each code's 90-day global period, resulting in work RVUs of 15.39 and 15.85, respectively. Although these RVUs are similar, the intraservice times are not. CPT code 35606 has an intraservice time of 145

minutes compared with 120 minutes for CPT code 37217. To address the variation in intraservice times, we calculated a work RVU for CPT code 37217 that results in its work RVU having the same relationship to its time as does CPT code 35606. This results in a work RVU of 13.12 for the intraservice time. Adding back the RVUs for the visits results in a total work RVU of 19.73. This value, along with the RVUs of the other comparison codes used by the AMA RUC (CPT codes 37215 and 35301), supports our decision to establish a CY 2014 interim final work RVU of 20.38, the 25th percentile of the survey. We believe that this work RVU of 20.38 more accurately reflects the work involved and maintains relatively among the other codes involving similar work.

(6) Transcatheter Placement Intravascular Stent (CPT Code 37236, 37237, 37238, and 37239)

For CY 2014, the CPT Editorial Panel deleted four intravascular stent placement codes and created four new bundled codes, CPT codes 37236, 37237, 37238, and 37239.

We agreed with the AMA RUC recommendations for all of the codes in the family except CPT code 37239. The AMA RUC recommended a work RVU of 3.34 for CPT code 37239, which they crosswalked to the work value of 35686 (Creation of distal arteriovenous fistula during lower extremity bypass surgery (non-hemodialysis) (List separately in addition to code for primary procedure)). CPT code 37239 is the add-on code to 37238 for placement of an intravascular stent in each additional vein. The AMA RUC valued placement of a stent in the initial artery (CPT code 37236) at 9.0 work RVUs and its corresponding add-on code (37237) for placement of a stent in an additional artery at 4.25 work RVUs. After review, we believe that the ratio of the work of placement of the initial stent and additional stents would be the same regardless of whether the stent is placed in an artery or a vein, and that the appropriate ratio is found in the AMA RUC-recommended work RVUs of CPT codes 37236 and 37237. To determine the work RVU for CPT code 37239, we applied that ratio to the AMA RUC-recommended work RVU of 6.29 for CPT code 37238. Therefore, we are assigning an interim final work RVU of 2.97 to CPT code 37239 for CY 2014.

(7) Embolization and Occlusion Procedures (CPT Codes 37241, 37242, 37243, and 37244)

For CY 2014, the CPT Editorial Panel deleted CPT code 37204 (transcatheter occlusion or embolization (eg, for tumor destruction, to achieve hemostasis, to occlude a vascular malformation), percutaneous, any method, non-central nervous system, non-head or neck)) and created four new bundled codes to describe embolization and occlusion procedures, CPT codes 37241, 37242, 37423, and 37244.

We agreed with the AMA RUC recommendations for CPT codes 37241 and 37244. However, we disagree with the AMA RUC-recommended work RVU of 11.98 for CPT code 37242. The AMA RUC recommended a direct crosswalk to CPT code 34833 (Open iliac artery exposure with creation of conduit for delivery of aortic or iliac endovascular prosthesis, by abdominal or retroperitoneal incision, unilateral) because of the similarity in intraservice time. The service described by CPT code 37242 was previously reported using CPT codes 37204 (Transcatheter occlusion or embolization (eg., for tumor destruction, to achieve hemostasis, to occlude a vascular malformation), percutaneous, any method, noncentral nervous system, non-head or neck, 75894 (Transcatheter therapy, embolization, any method, radiological supervision and interpretation), and 75898 (Angiography through existing catheter for follow-up study for transcatheter therapy, embolization or infusion, other than for thrombolysis). The intraservice time for CPT code 37204 is 240 minutes and the work RVU is 18.11. The AMA RUCrecommended intraservice time for CPT code 37242 is 100 minutes. We believe that the AMA RUCrecommended work RVU does not adequately consider the substantial decrease in intraservice time for CPT code 37242 as compared to CPT code 37204. Therefore, we believe that the survey's 25th percentile work RVU of 10.05 is consistent with the decreases in intraservice time and more appropriately reflects the work of this procedure.

We also disagree with the AMA RUC-recommended work RVU of 14.00 for CPT code 37243, which the AMA RUC crosswalked from CPT code 37244, which has a work RVU of 14.00. The AMA RUC stated that work RVU of CPT codes 37243 and 37244 should be the same despite a 30-minute intraservice time difference between the codes because the work of CPT code 37244 (recommended intraservice time of 90 minutes) was more intense than CPT code 37243 (recommended intraservice time of 120 minutes). This service was previously reported using CPT codes 37204, 75894 and 75898; or

37210 (Uterine fibroid embolization (UFE, embolization of the uterine arteries to treat uterine fibroids, leiomyoma), percutaneous approach inclusive of vascular access, vessel selection, embolization, and all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the procedure). The current intraservice time for CPT code 37204 is 240 minutes and the work RVU is 18.11. The current intraservice time for CPT code 37210 is 90 minutes and the work RVU is 10.60. The AMA RUC-recommended intraservice time for 37243 is 120 minutes. We do not believe that the AMA RUC-recommended work RVU adequately considers the substantial decrease in intraservice time for CPT code 37243 as compared to CPT code 37204. We also note that the AMA recognized that CPT code 37243 is less intense than CPT code 37244. Therefore, we believe that the survey's 25th percentile work RVU of 11.99 more appropriately reflects the work required to perform this service.

(8a) Gastrointestinal (GI) Endoscopy (CPT Codes 43191-43453)

In CY 2011, numerous esophagoscopy codes were identified as potentially misvalued because they were on the CMS multi-specialty points of comparison list. For CY 2014, the CPT Editorial Panel revised the code sets for these services. The AMA RUC submitted recommendations for 65 codes that describe esophagoscopy, esophagogastroduodenoscopy (EGD), and endoscopic retrograde cholangiopancreatography (ERCP) of the esophagus, stomach, duodenum, and pancreas/gall bladder.

In valuing this revised set of codes, we note that the AMA RUC recommendations included information demonstrating significant overall reduction in time resources associated with furnishing these services. In the absence of information supporting an increase in intensity, we would expect that the work RVUs would decrease if there are reductions in time. However, the AMA RUC-recommended work RVUs do not reflect overall reductions in work RVUs proportionate to the reductions in time. Therefore, we questioned the recommended work RVUs unless the recommendations included information indicating that the intensity of the work had increased.

We note that in assigning values that maintain the appropriate relativity throughout the PFS, it is extremely important to review a family of services together and we aim to address recommendations

regarding potentially misvalued codes in the first possible rulemaking cycle. Therefore, we are establishing interim final values for these codes for CY 2014 although we do not have the AMA RUC recommendations for the remaining lower GI tract codes. We expect to receive these recommendations in time to include them in the CY 2015 final rule with comment period. At that time, we may revise the interim final values established in this final rule with comment period to address any family relativity issues that may arise once we have more complete information for the entire family.

The AMA RUC used a number of methodologies in valuing these codes. These include accepting survey medians or 25th percentiles, crosswalking to other codes, and calculating work RVUs using the building block methodology. These are reviewed in section II.E.1. above. The AMA RUC also made extensive use of a methodology that uses the incremental difference in codes to determine values for many of these services. This methodology, which we call the incremental difference methodology, uses a base code or other comparable code and considers what the difference should be between that code and another code by comparing the differentials to those for other similar codes. Many of the procedures described within the esophagoscopy subfamily have identical counterparts in the esophagogastroduodenoscopy (EGD) subfamily. For instance, the base esophagoscopy CPT code 43200 is described as "Esophagoscopy, flexible, transoral; diagnostic, including collection of specimen(s) by brushing or washing when performed." The base EGD CPT code 43235 is described as "Esophagogastroduodenoscopy, flexible, transoral; diagnostic, with collection of specimen(s) by brushing or washing, when performed." In valuing other codes within both subfamilies, the AMA RUC frequently used the difference between these two base codes as an increment for measuring the difference in work involved in doing a similar procedure utilizing esophagoscopy versus utilizing EGD. For example, the EGD CPT code 43239 includes a biopsy in addition to the base diagnostic EGD CPT code 43235. The AMA RUC valued this by adding the incremental difference in the base esophagoscopy code over the base EGD CPT code to the value it recommended for the esophagoscopy biopsy, CPT code 43202. With some variations, the AMA RUC extensively used this incremental difference methodology in valuing subfamilies of codes. We have made use of similar methodologies, in addition to the methodologies

listed above, in establishing work RVUs for codes in this family. We have also made use of an additional methodology not typically utilized by the AMA RUC. As noted above in this section, we believe that the significant decreases in intraservice and total times for these services should result in corresponding changes to the work RVUs for the services. In keeping with this principle, we chose, in some cases, to decrement the work RVUs for particular codes in direct proportion to the decrement in time. For example, for a CPT code with a current work RVU of 4.00 and an intraservice time of 20 minutes that decreases to 15 minutes following the survey, we might have reconciled the 25 percent reduction in overall time by reducing the work RVU to 3.00, a reduction of 25 percent.

(8b) Esophagoscopy

The rigid and flexible esophagoscopy services are currently combined into one code, but under the new coding structure the services are separated into rigid transoral, flexible transnasal and flexible transoral procedure CPT codes.

(8c) Rigid Transoral Esophagoscopy

To determine the interim final values for the rigid transoral esophagoscopy codes, CPT codes 43191, 43192, 43193, 43194, 43195, and 43196, we considered the AMA RUC-recommended intraservice times and found that the surveys showed that half of the rigid transoral esophagoscopy codes had 30 minutes of intraservice time and a work RVU survey low of 3.00, a ratio of 1 RVU per 10 minutes (1 work RVU/10 minutes). This ratio was further supported by the relationship between the CY 2013 work value of 1.59 RVUs for CPT code 43200 (Esophagoscopy, rigid or flexible; diagnostic, with or without collection of specimen(s) by brushing or washing (separate procedure)) and its intraservice time of 15 minutes. Based upon the 1 work RVU/10 minutes ratio, we are establishing CY 2014 interim final work RVU of 2.00 for CPT code 43191, 3.00 for CPT code 43193, 3.00 for CPT code 43194, 3.00 for CPT code 43195, and 3.30 for CPT code 43196.

For CPT code 43192, the 1 work RVU/10 minute ratio resulted in a value that was less than the survey low, and thus did not appear to work appropriately for this procedure. Therefore, we are establishing a CY 2014 interim final work RVU for CPT code 43192 of 2.45 based upon the survey low.

(8d) Flexible Transnasal Esophagoscopy

In recommending work RVUs for the two CPT codes 43197 and 43198, which describe flexible transnasal services, the AMA RUC recommended the same work RVUs as it recommended for the corresponding flexible transoral CPT codes (43200 and 43202). We believe these recommendations overstate the work involved in the transnasal codes since, unlike the transoral codes, they are not typically furnished with moderate sedation. Therefore, to value CPT code 43197 and 43198, we removed 2 minutes of the pre-scrub, dress and wait preservice time from the calculation of the work RVUs that we are establishing for CY 2014 for CPT codes 43200 and 43202. We are establishing CY 2014 interim final values of 1.48 for CPT code 43197 and 1.78 for CPT code 43198.

(8e) Flexible Transoral Esophagoscopy

We established values for CPT codes 43216 through 43226 based on the AMA RUC recommendations.

We used CPT code 43200 as the base code for evaluating all the flexible esophagoscopy services. The CY 2013 code descriptor for 43200 includes both flexible and rigid esophagoscopy, while for CY 2014, the descriptor has been revised to include only flexible esophagoscopy. Despite this change in the code descriptor for CY 2014, the AMA RUC-recommended maintaining a work RVU of 1.59 for this code. However, we believe that the rigid esophagoscopy, described by the new CPT code 43191, is a more difficult procedure and by removing the rigid service from CPT code 43200 the intensity of services described by the revised CPT code 43200 are lower than the intensity of services described by the existing code. To establish an appropriate interim final value for the new code, we followed the 1 work RVU per 10 minutes of intraservice time methodology described above resulting in an interim final work RVU of 1.50 for the service. This interim final work RVU valuation is further supported by the AMA RUC's recommendation that would decrease total time from 55 minutes to 52 minutes.

We believe that the work value difference between CPT code 43200 and 43202 as recommended by the AMA RUC is correct. Therefore, we added the difference in the AMA RUC recommended values for CPT codes 43200 and 43202, 0.30 RVUs, to CPT code 43200, resulting in a work RVU of 1.80 for

CPT codes 43201.. We note that the resulting difference between 43200 and 43201 of 0.30 RVUs is also similar to the 0.31 difference between the values the AMA RUC recommended for these two codes.

We also believe that the work involved in CPT code 43201 is similar to the work involved in CPT code 43202. Accordingly we are establishing a CY 2014 interim final work RVU of 1.80.

For CPT code 43204, the AMA RUC recommended a work RVU of 2.89. We believe that this code is similar to CPT code 43201 in that both codes involve injections in the esophagus. However, CPT code 43204 has 20 minutes of intraservice time compared to 15 minutes for CPT code 43201. Applying this increase in intraservice time to the work RVU that we are establishing for CPT code 43201 results in a work RVU of 2.40 for this code. The AMA RUC recommended a work RVU of 3.00 for CPT code 43205, an increment of 0.11 RVUs over its recommended value for CPT code 43204. Both of these codes involve treatment of esophageal varices. We agree with that increment and are adding that to our CY 2014 interim final work RVU of 2.51 for CPT code 43205.

In establishing interim final work RVUs for CPT code 43211, we followed the methodology used by the AMA RUC to develop its recommendation. The AMA RUC decreased the work RVU of the corresponding esophagogastroduodenoscopy (EGD for mucosal resection), CPT code 43254, by the difference between the base esophagoscopy code 43200 and the base EGD code 43235, which is 0.67 RVU. Reducing our CY 2014 interim final work RVU of 4.88 for CPT code 43254 by this difference results in a CY 2014 interim final work RVU of 4.21 for CPT code 43211.

Since CPT code 43212 has almost identical times and intensities as CPT code 43214, we crosswalked the work RVU from our CY 2014 interim final work RVU of 3.38.

In valuing CPT code 43213, we believe it is comparable to CPT code 43200, but has intraservice time of 45 minutes, while CPT code 43200 has only 20 minutes. We are establishing a CY 2014 interim final work RVU of 4.73, which is based upon the difference in intraservice time between the two codes

CPT code 43214 is esophageal dilatation using fluoroscopic guidance. We believe that the service described by CPT code 43214 is similar in intensity and intraservice time to CPT code 31622

(Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with cell washing, when performed (separate procedure)), another endoscopic code using fluoroscopic guidance. However, CPT code 43214 includes an endoscopic dilation in addition to the fluoroscopic guided endoscopy. Therefore, we added the incremental increase between the work RVU of the esophagoscopy base code for dilation without fluoroscopic guidance, CPT code 43220, and the base code to the work RVU for CPT code 31622 and are establishing a CY 2014 interim final work RVU of 3.38 for CPT code 43214.

We believe that the time and work for CPT 43215 are identical to those for CPT code 43205.

Therefore, we crosswalked the work RVU for CPT code 43215 to CPT code 43205, and are establishing a CY 2014 interim final work RVU of 2.51.

For current CPT code 43227, the survey reflected a decrease in intraservice time from the current, 36 minutes to 30 minutes. The AMA RUC recommended a small decrease in RVUs, but not one that was proportionate to the difference in intraservice time. Therefore, we decreased the current work RVU proportionate to the decrease in intraservice time, resulting in a CY 2014 interim final work RVU of 2.99.

CPT code 43231 is a basic esophagoscopy procedure done with endoscopic ultrasound. We disagree with the AMA RUC recommendation to maintain the current work RVU of 3.19, despite a decrease in intraservice time. Instead, we used the work RVU of another endoscopic code using endoscopic ultrasound to value the incremental difference in work between this service and the esophagoscopy base code. CPT code 31620 (Endobronchial ultrasound (EBUS) during bronchoscopic diagnostic or therapeutic intervention(s) (List separately in addition to code for primary procedure[s])) is an add-on code for EBUS to other bronchoscopy codes, with a current work RVU of 1.40. We added this EBUS work RUV to the work RVU of base esophagoscopy code 43200 and are establishing a CY 2014 interim final work RVU of 2.90.

For CPT code 43232, we believe that the work value difference between CPT code 43231 and 43232 as recommended by the AMA RUC is correct. We added that difference of 0.64 work RVUs to

our CY 2014 interim final work RVU for CPT code 43231 to arrive at our CY 2014 interim final work RVU of 3.54 for CPT code 43232.

CPT code 43229 has similar times and intensity to CPT code 43232 and therefore, we directly crosswalked the work value of CPT code 43229 to CPT code 43232, resulting in a CY 2014 interim final work RVU of 3.54.

(8f) Esophagogastroduodenoscopy (EGD)

Various EGD codes were identified as potentially misvalued through the multi-specialty point of comparison, high expenditures, and fastest growing screens. The AMA RUC recommended values for all EGD codes. We agreed with the AMA RUC recommended values and are establishing CY 2014 interim final work RVUs for CPT codes 43240, 43241, 43243, 43244, 43245, 43248, 43249, 43250, and 43251 based on its recommendations.

In reviewing the base EGD code, CPT code 43235, we determined that we agreed with the AMA RUC's recommended work RVU difference between this EGD base code and the esophagoscopy base code, CPT 43200. We applied this difference to our CY 2014 interim final work RVU of 1.50 for CPT code 43200 and are establishing a CY 2014 interim final RVU of 2.17 for CPT code 43235.

CPT code 43233 is an identical procedure to CPT code 43214 except that it uses EGD rather than esophagoscopy. We added the additional work RVU of furnishing an EGD as compared to an esophagoscopy to our CY 2014 interim final work RVU of 3.38 for CPT code 43214, resulting in a CY 2014 interim final work RVU of 4.05 for CPT 43233.

CPT code 43236 is the EGD equivalent of the esophagoscopy CPT code 43201. In valuing CPT code 43236, the AMA RUC used the incremental difference methodology using CPT codes 43200 and 43201 and added that difference to its recommended work value for CPT code 43235 to arrive at its recommended RVU of 2.57 for CPT code 43236. We used the same methodology but instead of using the AMA RUC recommended work RVU for CPT code 43235, we used our CY 2014 interim final value of 2.17 for CPT code 43235. We are establishing a CY 2014 interim final work RVU of 2.47 for CPT code 43236.

CPT code 43237 is the EGD equivalent to the esophagoscopy CPT code 43231. We do not believe that the AMA RUC-recommended work RVU adequately accounts for the 20 percent decrease from current time to the AMA RUC-recommended intraservice time. Therefore, we applied an incremental difference methodology as discussed above for CPT code 43233. We used the comparable esophagoscopy code 43231 and added its CY 2014 interim final work RVUs to the incremental value of a base EGD over the base esophagoscopy, resulting in a CY 2014 interim final work RVU of 3.57 for CPT code 43237.

CPT code 43238 is the EGD equivalent to the esophagoscopy CPT code 43232. We valued this code similarly to CPT code 43237 using the incremental difference approach. We do not believe that the AMA RUC recommended RVU adequately accounts for the 36 percent decrease in intraservice time. We used the CY 2014 interim final work RVU for the comparable esophagoscopy CPT code 43232 and added that to that the incremental work RVU of an EGD over esophagoscopy, resulting in a CY 2014 interim final work RVU of 4.11 for CPT code 43238.

CPT code 43239 is the EGD equivalent to the esophagoscopy CPT code 43202 and we used the incremental difference methodology described above. We do not believe that the AMA RUC recommended RVU adequately accounts for the 56 percent decrease in intraservice time. We used the CY 2014 interim final work RVU for the comparable esophagoscopy code 43202 and added that to the incremental work RVU value of an EGD over esophagoscopy, resulting in a work RVU of 2.47, which we are establishing as the CY 2014 interim final work RVU for CPT code 43239.

CPT code 43242 is an equivalent service to CPT code 43238 except that CPT code 43242 includes diagnostic services in a surgically altered GI tract. The AMA RUC recommendation used a methodology that took the increment between CPT code 43238 and CPT code 43237, which is an ultrasound examination of a gastrointestinal (GI) tract that has not been surgically altered. The AMA RUC then applied that difference in its recommended work RVUs for these two codes to CPT code 43259, which is an ultrasound of a GI tract that has been surgically altered. We agree with that methodology but instead applied our CY 2014 interim final work RVUs for those codes. Accordingly, we are establishing a CY 2014 interim final RVU of 4.68 for CPT code 43242.

In valuing CPT code 43246, we note that the work and time are very similar to CPT code 43255. Therefore, we directly crosswalked the service to the CY 2014 interim final work RVU of CPT code 43255 and are establishing a CY 2014 interim final value of 3.66.

CPT code 43247 is the EGD equivalent to the esophagoscopy CPT code 43215. In valuing this code, the AMA RUC applied the increment between CPT code 43200 and 43215 to the EGD base CPT code 43235 to arrive at its recommended RVU of 3.27. We agree with this methodology but applied the values we have established for these codes, resulting in a work RVU of 3.18 for CPT code 43247.

In valuing CPT code 43253, the AMA RUC applied the same methodology as it used in valuing CPT code 43242, resulting in a recommended RVU of 5.39. We agree with that methodology, but instead of using the AMA RUC-recommended values, we are using our CY 2014 interim final work RVUs. We are establishing a CY 2014 interim final work RVU of 4.68 for CPT code 43253.

CPT code 43254 is the EGD equivalent to the esophagoscopy CPT code 43211. The AMA RUC-recommended a work RVU of the survey's 25th percentile of 5.25. We believe that this overstates the work involved in this code and that the incremental methodology used by the AMA RUC for many of these codes is more appropriate. Thus, we applied the incremental difference methodology between the base EGD and esophagoscopy codes to the equivalent esophagoscopy CPT code 43211 and are establishing a CY 2014 interim final RVU of 4.88.

CPT code 43255 is the EGD equivalent to the esophagoscopy CPT code 43227. We do not believe that the AMA RUC-recommended 13 percent work RVU decrease adequately accounts for the 44 percent decrease in intraservice time. Therefore, we applied the incremental difference methodology, using our CY 2014 interim final values and the comparable esophagoscopy code, CPT code 43227. We are establishing a CY 2014 interim final work RVU of 3.66 for CPT code 43255.

CPT code 43257 is a CY 2013 code for which the AMA RUC recommended the survey's 25th percentile. We note that the service has an identical intraservice time and similar intensity to CPT code 43238. Thus, we directly crosswalked the work RVU from CPT code 43238 to CPT code 43257. We are

establishing a CY 2014 interim final work RVU of 4.11 for CPT code 43257, which is consistent with the 25 percent reduction from current intraservice time.

In valuing CPT code 43259, the AMA RUC recommended the survey's 25th percentile RVU of 4.74. We disagree with that value and note that the intraservice time has decreased 35 percent and the total time has decreased 20 percent. Applying the intraservice time decrease to the CY 2013 work RVU would result in an RVU of 3.38. We believe that value does not maintain the appropriate rank order with the other EGD codes. Adjusting the current RVU to account for the reduction in total time results in a work RVU of 4.14. We believe that this work RVU more accurately values the work involved in this service. Thus, we are establishing a CY 2014 interim final RVU of 4.14 for this code.

CPT code 43266 is the EGD equivalent to the esophagoscopy CPT code 43212. In valuing CPT code 43266, the AMA RUC recommended the survey's 25th percentile RVU of 4.40, higher than the current value of 4.34 even though the intraservice time decreased from 45 minutes to 40 minutes. We disagree with this recommended work RVU. Therefore, we used the incremental difference methodology and added the difference in work RVUs between the base esophagoscopy code and the base EGD code to the equivalent esophagoscopy CPT code 43212 for an RVU of 4.05. Thus, we are establishing a CY 2014 interim final work RVU of 4.05 for CPT code 43266.

CPT code 43270 is the EGD equivalent to the esophagoscopy CPT code 43229. The AMA RUC recommended the survey's 25th percentile work RVU of 4.39. We disagree with this value and believe that utilizing the incremental difference methodology more accurately determines the appropriate work for this service. For CPT code 43270, we added the difference in work RVUs between the base EGD code over the base esophagoscopy code to our CY 2014 interim final work RVU for CPT 43229, resulting in a work RVU of 4.21. Thus, we are establishing a CY 2014 interim final value of 4.21 for CPT code 43270.

In CY 2011, several endoscopic retrograde cholangiopancreatography (ERCP) codes were identified by CMS through the multi-specialty points of comparison screen. The AMA RUC provided recommendations for seven current codes and five new codes. CPT codes 43260 -43265 and 43273 -

43278 were reviewed. We agreed with the AMA RUC-recommended values for CPT codes 43260, 43261, 43262, 43264, 43265, 43273, 43275, and 43277 as shown on Table 27.

The AMA RUC recommended that the work RVU for CPT code 43263 be maintained at its current RVU of 7.28 in spite of a 25 percent decrease to its recommended intraservice time for this code. This code has identical times to CPT code 43262 for which the AMA RUC recommended a decrease in the work RVU from its current value of 7.38 to 6.60, consistent with the decrease in time. We believe that this reduction more accurately reflects the work involved in this code, so we crosswalked the work RVU for CPT code 43263 to CPT code 43262. We are establishing a CY 2014 interim final work RVU of 6.60 for CPT code 43263.

CPT code 43274 is a new code involving stent placement and sphincterotomy. The AMA RUC valued this code by adding the increment of a sphincterotomy and stent placement to the work RVU of the base ERCP, CPT code 43260, resulting in an AMA RUC-recommended work RVU of 8.74. We agree with this methodology, except we have used our CY 2014 interim final work RVUs. We are establishing an interim final RVU of 8.48 for CPT code 43274.

CPT code 43276 is a new code without previous physician times to compare that involves the removal and replacement of a stent. The AMA RUC developed its recommendation using the incremental difference methodology. It determined the incremental work RVU associated with removing a foreign body by comparing CPT code 43215 to the base esophagoscopy code, CPT code 43200. It also determined the incremental value of placing a stent with esophagoscopy, CPT code 43212, over the base esophagoscopy, CPT code 43200. By adding these two increments to the work RVU of the ERCP base code, CPT code 43260, the AMA recommended a work RVU for CPT code 43276 of 9.10. The median survey value was 9.88 and the survey's 25th percentile was 6.95. The combination of 60 minutes of intraservice time with an RVU of 9.10 is not comparable with other ERCP codes. For CPT code 43274, for example, the AMA RUC recommended 68 minutes intraservice time and a work RVU of 8.74. We accepted the AMA RUC recommendations for CPT code 43265 of 78 minutes intraservice time and a work RVU of 8.03. Both CPT codes 43262 and 43263 have intraservice times of 60 minutes and a CY

2014 interim final work RVU of 6.60. Based on these comparisons, we believe that the AMA RUC recommendation for this code of 9.10 is inconsistent with the RVUs assigned to codes that describe similar services with similar intraservice times. Therefore, we are using the incremental difference methodology to arrive at the appropriate work RVU. CPT code 43275 describes the removal of a stent using ERCP. We used CPT code 43275 with a CY 2014 interim final work RVU of 6.96 and added the incremental difference of placing a stent utilizing esophagoscopy, CPT code 43212, over the base esophagoscopy code CPT code 43200. We believe that this valuation approach results in values that are more consistent with other codes in this family than the AMA RUC recommendation. We are establishing a CY 2014 interim final RVU of 8.84 for CPT code 43276.

CPT code 43277 is a new code for CY 2014, which describes ERCP with dilation and if furnished, sphincterotomy. The AMA RUC recommended a work RVU of 7.11 RVU. The AMA RUC determined this value using an incremental approach. Specifically, the work RVU for dilation was calculated as the difference between the esophagoscopy dilation code (CPT code 43220) and the esophagoscopy base code, CPT code 43200, and the sphincterotomy work RVU was calculated as the difference between the base ERCP code, CPT 43260, and the ERCP sphincterotomy code, CPT code 43262. By adding these two values to the work RVU of CPT code 43260, the AMA RUC calculated its recommended work RVU of 7.11. The survey's 25th percentile is 7.00.

Currently, ERCP sphincterotomy is billed using a single code, CPT code 43262, and duct dilation using ERCP is currently billed using CPT code 43271. Adding together the current work RVUs for these two codes results in a RVU of 8.81. The total combined intraservice time for these two codes is 90 minutes. Since the new CPT code 43277 has an intraservice time of only 70 minutes, we applied the percentage decrease in time to the current combined work RVU for CPT 43262 and 43271 of 8.81, resulting in a work RVU of 6.85. Although this value reflects a proportional reduction in intraservice time between the current codes and the time presumed for the AMA RUC recommendation, we believe that a work RVU of 6.85 does not adequately reflect the intensity of this service and are therefore establishing an interim final RVU for CPT code of 43277 of 7.00, which is the survey's 25th percentile.

CPT code 43278 is a new code involving lesion ablation. The AMA RUC valued this code by adding the incremental work RVU difference between the base esophagoscopy code and the esophagoscopy ablation code, CPT code 43229, to the base ERCP code, resulting in a RVU of 8.08. We agree with this methodology. However, using our CY 2014 interim final values we are establishing a CY 2014 interim final work RVU of 7.99.

(8h) Dilation of Esophagus

We agree with the AMA RUC recommended values for the dilation of the esophagus, CPT codes 43450 and 43453, as shown on Table 27.

(9) Transplantation of Kidney (CPT Code 50360)

We received an AMA RUC work RVU recommendation of 40.90 for CPT code 50360 which included an increase in the service's intraservice time, from 183 minutes to 210 minutes. We also note that there is a significant decrease in the number of AMA RUC-recommended visits in the global period for this procedure.

In CY 2006, the work RVU for CPT 50360 was 31.48. In CY 2007 and CY 2010, the work RVUs for all services with global periods, including CPT code 50360, were increased to take into account increases in the work RVUs for E/M services. These changes resulted in the current work RVU for CPT code 50360 of 40.90. We note that this increase was based on an assumption of 32 visits in the global period. Based upon information that we now have, it appears that an assumption of 10 visits may have been more appropriate. If we had used an assumption of 10 visits when adding E/M services in 2007 and 2010, the current work RVU would be 34.68.

In determining a CY 2014 interim final work RVU, we began with the 34.68 work RVU value. The AMA RUC recommended a 14.75 percent increase in intraservice time, from 183 min to 210 min. Applying this ratio to the refined base work RVU of 34.68 results in a new base work RVU of 39.80. Adding the changes in work RVU resulting from the changes in the preservice and postservice times recommended by the AMA RUC results in an interim final work RVU of 39.88 for CPT code 50360. (10) Spinal Injections (CPT Codes 62310, 62311, 62318, and 62319)

For CY 2014, we received AMA RUC recommendations for CPT codes 62310, 62311, 62318, and 62319. Although the AMA RUC recommendations show a significant reduction in intraservice and total times for the family, the recommended work RVUs do not reflect a similar decrease.

For CPT code 62310, we disagree with the work RVU of 1.68 recommended by the AMA RUC because the reduction from the current work is not comparable to the 63 percent reduction in time being recommended by the AMA RUC. We, however, agree that the methodology used by the AMA RUC to develop a recommendation was appropriate. Using this methodology, we calculated the difference in the AMA RUC recommendations for CPT 62310 and 62318 and subtracted this from our CY 2014 interim work RVU for CPT 62318, which results in a work RVU of 1.18, which we are establishing as the CY 2014 interim final work RVU for CPT code 62310.

The AMA RUC recommended maintaining the current work RVU for CPT code 62311 of 1.54 even though its recommended intraservice time decreased 50 percent. We disagreed with this approach. To determine the CY 2014 interim final work RVU we subtracted the difference between the AMA RUC-recommended work RVUs of 62311 and 62319 from our CY 2014 interim final work RVU for CPT code 62319. We believe that the resultant work RVU of 1.17 is a better approximation of the work involved in CPT code 62311.

CPT code 62318 currently has an intraservice time of 20 minutes and a work RVU of 2.04. The intraservice time reduced by 25 percent but the AMA RUC recommended no change in the work RVU. The low value of the survey is 1.54, which is consistent with the reduction in intraservice time. Therefore, we are establishing an interim final RVU for CPT code 62318 of 1.54.

The AMA RUC recommended a 50 percent decrease in intraservice time for CPT 62319 but no change in the work RVU. Similar to the CPT code 62318, we believe the low value of 1.50 more accurately represents the work involved in the code and the significant reduction in intraservice time.

(11) Laminectomy (CPT Codes 63047 and 63048)

We identified CPT code 63047 through the high expenditure procedure code screen. For CY 2014, we received AMA RUC recommendations on CPT codes 63047 and 63048.

In reviewing the AMA RUC recommendations for these codes, we determined that to appropriately value these codes, we need to consider the other two codes in this family: CPT codes 63045 (Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [eg, spinal or lateral recess stenosis]), single vertebral segment; cervical) and 63046 (Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [eg, spinal or lateral recess stenosis]), single vertebral segment; thoracic). Since the AMA RUC did not submit recommendations for these codes, we are valuing CPT codes 63047 and 63048 on an interim final basis for CY 2014 at work RVUs of 15.37 and 3.47, respectively, based upon the AMA RUC recommendations. We note that expect to review these values in concert with the AMA RUC recommendations for CPT codes 63045 and 63046. (12) Chemodenervation of Neck Muscles (CPT Codes 64616 and 64617)

For CY 2014, we received AMA RUC recommendations for two new chemodenervation codes, CPT codes 64616 and 64617, which replace CPT code 64613 (chemodenervation of muscle(s); neck muscle(s) (eg, for spasmodic torticollis, spasmodic dysphonia)). We disagree with the AMA RUC-recommended work RVUs of 1.79 for CPT code 64616 and 2.06 for CPT code 64617. We do not think that these recommended values account for the absence of the outpatient visit that was included in the predecessor code, CPT 64613. To adjust for this, we subtracted the 0.48 work RVUs associated with the outpatient visit from the 2.01 work RVU of the predecessor code, CPT code 64613; resulting in a work RVU of 1.53, which we are assigning as an interim final value for CPT 64616.

CPT code 64617 is chemodenervation of the larynx and includes EMG guidance when furnished. The EMG guidance CPT code 95874 (Needle electromyography for guidance in conjunction with chemodenervation (List separately in addition to code for primary procedure)) has a work RVU of 0.37. To calculate the work RVU for CPT 64617 we added the work RVU for CPT 95874, EMG guidance, to the 1.53 work RVU for CPT 64616, which results in a work RVU of 1.90.

Therefore, on an interim final basis for CY 2014, we are assigning a work RVU of 1.53 to CPT code 64616 and 1.90 to CPT code 64617.

(13) Chemodenervation of Extremity or Trunk Muscles (CPT Codes 64642, 64643, 64644, 64645, and 64647)

For CY 2014, the CPT Editorial Panel created six new codes to more precisely describe chemodenervation of extremity and trunk muscles. We assigned CY 2014 interim final work RVUs for four of these CPT codes (64642, 64644, 64646 and 64647), based upon the AMA RUC recommendations.

CPT Codes 64643 and 64645 are add-on codes to CPT codes 64642 and 64644, respectively. We disagree with the AMA RUC-recommended work RVUs of 1.32 for CPT code 64643 and 1.52 for CPT code 64645. We agree with the AMA RUC that the intraservice times for each base code and its add-on code should be the same. However, the AMA RUC-recommendations for the add-on codes contain 19 minutes less time than the base codes because of decreased preservice and post- times in the add-on codes. Therefore, we are adjusting the add-on codes by subtracting the RVUs equal to 19 minutes of preservice and postservice from the AMA RUC recommended work RVU for each base code to account for the decrease in time for performing the add-on service. Using the methodology outlined above, we are assigning a CY 2014 interim final work RVU for CPT code 64643 of 1.22 and a work RVU for CPT code 64645 of 1.39.

We are basing the global period for these codes on their predecessor code, CPT code 64614 (chemodenervation of muscle(s); extremity and/or trunk muscle(s) (eg, for dystonia, cerebral palsy, multiple sclerosis)), which is being deleted for CY 2014. Therefore, we are assigning these codes a 010-day global period.

(14) Cerumen Removal (CPT Code 69210)

This code was reviewed as a potentially misvalued code pursuant to the CMS high expenditure screen. The CPT Editorial Panel changed the code descriptor for removal of impacted cerumen from "1 or both ears" to "unilateral," effective January 1, 2014. The AMA RUC recommended a work RVU for this code of 0.58. In its recommendation to the AMA RUC, the specialty society stated that there was no information to determine how often the service was performed unilaterally but asserted, and the AMA RUC agreed, that the service was performed bilaterally 10 percent of the time. In determining its

recommendation, the AMA RUC applied work neutrality to the current work RVU of 0.61 to arrive at the recommended work RVU of 0.58 based upon the assertion that the code that was previously only reported once if furnished bilaterally, would now be reported for two units, due the descriptor change.

We disagree with the assumption by the AMA RUC that the procedure will be furnished in both ears only 10 percent of the time as the physiologic processes that create cerumen impaction likely would affect both ears. Given this, we will continue to allow only one unit of CPT 69210 to be billed when furnished bilaterally. We do not believe the AMA RUC's recommended value reflects this and therefore, we will maintain the CY 2013 work value of 0.61 for CPT code 69210 when the service is furnished.

(15) MRI Brain (CPT Code 70551, 70552, 70553, 72141, 72142, 72146, 72147, 72148, 72149, 72156, 72157, and 72158)

For CY 2014, the AMA RUC reviewed the family of magnetic resonance imaging (MRI) for the brain (CPT codes 70551, 70552, and 70553) and the family for MRI for the spine (CPT codes 72141, 72142, 72146, 72147, 72148, 72149, 72156, 72157, and 72158). We are assigning the AMA RUC-recommended work RVUs as CY 2014 interim final values for all of these codes except for CPT code 70553.

The AMA RUC found that the codes in these two families required a similar amount of work and valued the codes with similar work identically, except for CPT code 70553, which is the MRI code for brain imaging. CPT code 70553 is brain imaging without contrast followed by brain imaging with contrast. The AMA RUC recommended that the work RVU for this code remain at its current value of 2.36, while recommending that the work RVUs of CPT codes 72156, 72157 and 72158 be decreased to 2.29. These three codes are similar to CPT code 70553 in that they identify MRI services without contrast followed by contrast for the three sections of the spine—cervical, thoracic and lumbar. We agree with the AMA RUC that the work is similar for the two families of codes and that the codes should be valued accordingly. The AMA RUC-recommended value for CPT code 70553 is not consistent with the determination that these codes require a similar amount of work. Therefore, we are assigning a CY 2014 interim final work RVU of 2.29 to CPT code 70553.

(16) Molecular Pathology (CPT Code 81161)

The AMA RUC submitted a recommended value for CPT code 81161, a newly created molecular pathology code, for CY 2014. Consistent with our policy established in the CY 2013 final rule with comment period that molecular pathology codes are paid under the CLFS as lab tests, rather than under the PFS as physician services, we are assigning CPT code 81161, a PFS procedure status indicator of X (Statutory exclusion (not within definition of 'physician service' for physician fee schedule payment purposes. Physician Fee Schedule does not allow payment, but perhaps another Medicare Fee Schedule does)). (77 FR 68994-69002). As explained in the CY 2013 final rule with comment period, HCPCS code G0452 can be used under the PFS by a physician to bill for medically necessary interpretation and written report of a molecular pathology test, above and beyond the report of laboratory results.

The CPT Editorial Panel revised the existing immunohistochemistry code, CPT code 88342 and created a new add-on code 88343 for CY 2014. Current coding requirements only allow CPT code 88342 to be billed once per specimen for each antibody, but the revised CPT codes and descriptors would allow the reporting of multiple units for each slide and each block per antibody (88342 for the first antibody and 88343 for subsequent antibodies). We believe that this coding would encourage overutilization by allowing multiple blocks and slides to be billed.

To avoid this incentive, we are creating G0461 (Immunohistochemistry or immunocytochemistry, per specimen; first single or multiplex antibody stain) and G0462 (Immunohistochemistry or immunocytochemistry, per specimen; each additional single or multiplex antibody stain (List separately in addition to code for primary procedure)) to ensure that the services are only reported once for each antibody per specimen. We believe this will result in appropriate values for these services without creating incentives for overutilization.

We examined the AMA RUC recommendations for work RVUs CPT codes 88342 and 88343 in order to determine whether it would be appropriate to use these recommendations as the basis for establishing work RVUs for the new G-codes. To determine whether the AMA RUC-recommended work

RVUs were appropriate for use in valuing the new G-codes, we examined whether the change in descriptors between the CPT and G-codes would change the underlying assumptions regarding the physician work and resource costs of the typical services described by the codes. We note that the existing CPT code 88342 is to be reported per specimen, per antibody. To crosswalk the utilization for the service described by the current CPT code 88342 to the new CPT coding structure, the AMA RUC recommended that 90 percent of the utilization previously reported with CPT code 88342 would continue to be reported with as a single unit of 88342 and that 10 percent of the utilization previously reported with CPT code 88342 would be reported with the new add-on code, CPT code 88343. It seems clear, then, that in recommending values for the new services, the AMA RUC did not anticipate that any additional services would be reported despite the new descriptors that would allow for units to be reported for each block and each slide for each antibody. Therefore, we assume that the AMA RUC's recommended work RVUs and direct PE inputs for the new CPT codes were also developed with the assumption that the typical case would continue to be one unit reported per specimen, per antibody. Since the descriptors for the G-codes we are adopting in lieu of the new and revised CPT codes make explicit what appears to be the premise underlying the AMA RUC-recommended values for these services, we believe it is appropriate to use the AMA RUC recommendations for CPT codes 88342 and 88343 as the basis for establishing interim final work RVUs and direct PE inputs for the new G-codes for CY 2014.

Therefore, we are assigning an interim final work RVU of 0.60 for code G0461, which is the AMA RUC recommendation for CPT code 88342; and we are assigning an interim final work RVU of 0.24 for code G0462, which is the AMA RUC recommendation for CPT code 88343.

(18) Psychiatry (CPT Code 90863)

For CY 2013, the CPT Editorial Panel restructured the psychiatry/psychotherapy CPT codes allowing for separate reporting of E/M codes, eliminating the site-of-service differential, creation of CPT codes for crisis, and a series of add-on CPT codes to psychotherapy to describe interactive complexity and medication management. In CY 2013, the AMA RUC provided us with recommendations for the majority, but not all, of the updated psychiatry/psychotherapy CPT codes. Due to the absence of AMA

RUC recommendations for the entire family, we established interim final values for the codes based on a general approach of maintaining the previous values for the services, or as close to the previous values as possible, pending our receipt of recommended values for all codes in the new structure in CY 2014. See section II.E.2.a.ii.(25) of this final rule with comment period for a discussion of the finalization of the CY 2013 interim final RVUs.

For CY 2014, we received the outstanding AMA RUC recommendations for the psychiatry/psychotherapy CPT code family. We are establishing interim final work RVUs for CPT codes 90785, 90839, and 90840 based upon the AMA RUC's recommended work RVUs.

We are assigning CPT code 90863 a PFS procedure status indicator of I (Not valid for Medicare purposes. Medicare uses another code for the reporting of and the payment for these services.). The CPT Editorial Panel created CPT add-on code 90863 to describe medication management by a nonphysician when furnished with psychotherapy. As detailed in the CY 2013 final rule with comment period, clinical psychologists are precluded from billing Medicare for pharmacologic management services under CPT code 90863 because pharmacologic management services require some knowledge and ability to perform evaluation and management services, as some stakeholders acknowledged.

(19) Speech Evaluation (CPT Codes 92521, 92522, 92523, and 92524)

For CY 2014, the CPT Editorial Panel replaced CPT code 92506 (evaluation of speech, language, voice, communication, and/ or auditory processing) with four new speech evaluation codes, CPT codes 92521, 92522, 92523, and 92524, to more accurately describe speech-language pathology evaluation services.

We are assigning CY 2014 interim final work RVUs of 1.75 and 1.50 for CPT codes 92521 and 92522, respectively, as the HCPAC recommended.

For CPT code 92523, we disagree with the HCPAC-recommended work RVU of 3.36. In arguing that this service should have a higher work RVU than the survey median of 1.86, the affected specialty society stated that its survey results were faulty for this CPT code because surveyees did not consider all the work necessary to perform the service. We believe that the appropriate value for 60

minutes of work for the speech evaluation codes is reflected in CPT code 92522, for which the HCPAC recommended 1.50 RVUs. Because the intraservice time for CPT code 92523 is twice that for CPT code 92522, we are assigning a work RVU of 3.0 to CPT code 92523.

Similarly, since CPT codes 92524 and 92522 have identical intraservice time recommendations and similar descriptions of work we believe that the work RVU for CPT code 92524 should be the same as the work RVU for CPT code 95922. Therefore, we are assigning a work RVU of 1.50 to CPT code 92524.

Additionally, it is important to note that these codes are defined as "always therapy" services, regardless of the type of practitioner who performs them. As a result, CPT codes 92521, 92522, 92523 and 92524 always require a therapy modifier (GP, GO, or GN). Also, as noted in Addendum H, these codes will be subject to the therapy MPPR.

In accordance with longstanding Medicare policy, we also note that in general, we would expect that only one evaluation code would be billed for a therapy episode of care.

(20) Cardiovascular: Cardiac Catheterization (93582)

For CY 2014, we reviewed new CPT code 93582. Although the AMA RUC compared this code to CPT code 92941 (percutaneous transluminal revascularization of acute total/subtotal occlusion during acute myocardial infarction, coronary artery or coronary), which has a work RVU of 12.56 and 70 minutes of intraservice time, it recommended a work RVU of 14.00, the survey's 25th percentile. We agree with the AMA RUC that CPT code 92941 is an appropriate comparison code and believe that due to the similarity in intensity and time that the codes should be valued with the same work RVU. Therefore, we are assigning an interim final work RVU of 12.56 to CPT code 93582 for CY 2014.

(21) Duplex Scans (CPT Codes 93880, 93882, 93925, 93926, 93930, 93931, 93970, 93971, 93975, 93976, 93978 and 93979)

CPT Code 93880 was identified as a high expenditure procedure code and referred to the AMA RUC for review. As part of its recommendations, the AMA RUC included recommendations for CPT

code 93882. The AMA RUC recommended an increase in the work RVUs for 92880 and 92882 from 0.60 and 0.40 to 0.80 and 0.50, respectively.

In the 2013 PFS final rule with comment period, we reviewed 93925 (Duplex scan of lower extremity arteries or arterial bypass grafts; complete bilateral study) and 93926 (Duplex scan of lower extremity arteries or arterial bypass grafts; unilateral or limited study), which were identified by the AMA RUC as potentially misvalued because the time and PE inputs for these services were Harvard valued and these services have utilization of 500,000 service per year. We disagreed with the respective AMA RUC-recommended work RVUs of 0.90 and 0.70 and established interim final values of 0.80 and 0.50 instead.

We believe the AMA RUC-recommended values for these two sets of codes do not maintain the appropriate relative values within the family of duplex scans. In addition to these four codes, there are several other duplex scan codes that may fit within this family, including CPT codes: 93880 (Duplex scan of extracranial arteries; complete bilateral study), 93882 (Duplex scan of extracranial arteries; unilateral or limited study), 93925 (Duplex scan of lower extremity arteries or arterial bypass grafts; complete bilateral study), 93926 (Duplex scan of lower extremity arteries or arterial bypass grafts; unilateral or limited study), 93930 (Duplex scan of upper extremity arteries or arterial bypass grafts; complete bilateral study), 93931 (Duplex scan of upper extremity arteries or arterial bypass grafts; unilateral or limited study), 93970 (Duplex scan of extremity veins including responses to compression and other maneuvers; complete bilateral study), 93971 (Duplex scan of extremity veins including responses to compression and other maneuvers; unilateral or limited study), 93975 (Duplex scan of arterial inflow and venous outflow of abdominal, pelvic, scrotal contents and/or retroperitoneal organs; complete study), 93976 (Duplex scan of arterial inflow and venous outflow of abdominal, pelvic, scrotal contents and/or retroperitoneal organs; limited study), 93978 (Duplex scan of aorta, inferior vena cava, iliac vasculature, or bypass grafts; complete study) and 93979 (Duplex scan of aorta, inferior vena cava, iliac vasculature, or bypass grafts; unilateral or limited study).

We are concerned that the AMA RUC-recommended values for 93880 and 93882, as well as our interim final values for 93925 and 93926, do not maintain the appropriate relativity within this family and

we are referring the entire family to the AMA RUC to assess relativity among the codes and then recommend appropriate work RVUs. We also request that the AMA RUC consider CPT codes 93886 (Transcranial Doppler study of the intracranial arteries; complete study) and 93888 (Transcranial Doppler study of the intracranial arteries; limited study) in conjunction with the duplex scan codes in order to assess the relativity between and among these codes.

Therefore, we will maintain the CY 2013 RVUs for CPT codes 93880 and 93882 on an interim final basis until we receive further recommendations from the AMA RUC

(22) Ultrasonic Wound Assessment (CPT Code 97610)

For CY 2014, the AMA RUC reviewed new CPT code 97610. We are contractor pricing this code for CY 2014 as recommended by the AMA RUC. Although the code will be contractor priced, we are designating this service as a "sometimes therapy" service. Like other "sometimes therapy" codes, when a therapist furnishes this service all outpatient therapy policies apply.

(23) Interprofessional Telephone Consultative Services (CPT Code 99446, 99447, 99448, and 99449)

For CY 2014, the CPT Editorial Panel created CPT codes 99446 - 99449 to describe telephone/internet consultative services. The AMA RUC-recommended work RVUs for these codes. Medicare pays for telephone consultations about a beneficiary services as a part of other services furnished to the beneficiary. Therefore, for CY 2014 we are assigning CPT codes 99446, 99447, 99448, and 99449 a PFS procedure status indicator of B (Bundled code. Payments for covered services are always bundled into payment for other services, which are not specified. If RVUs are shown, they are not used for Medicare payment. If these services are covered, payment for them is subsumed by the payment for the services to which they are bundled (for example, a telephone call from a hospital nurse regarding care of a patient).)

- b. Establishing Interim Final Direct PE RVUs for CY 2014
- i. Background and Methodology

The AMA RUC provides CMS with recommendations regarding direct PE inputs, including clinical labor, supplies, and equipment, for new, revised, and potentially misvalued codes. We review the

AMA RUC-recommended direct PE inputs on a code-by-code basis, including the recommended facility PE inputs and/or nonfacility PE inputs. This review is informed by both our clinical assessment of the typical resource requirements for furnishing the service and our intention to maintain the principles of accuracy and relativity in the database. We determine whether we agree with the AMA RUC's recommended direct PE inputs for a service or, if we disagree, we refine the PE inputs to represent inputs that better reflect our estimate of the PE resources required to furnish the service in the facility and/or nonfacility settings. We also confirm that CPT codes should have facility and/or nonfacility direct PE inputs and make changes based on our clinical judgment and any PFS payment policies that would apply to the code.

We have accepted for CY 2014, as interim final and without refinement, the direct PE inputs based on the recommendations submitted by the AMA RUC for the codes listed in Table 28. For the remainder of the AMA RUC's direct PE recommendations, we have accepted the PE recommendations submitted by the AMA RUC as interim final, but with refinements. These codes and the refinements to their direct PE inputs are listed in Table 29.

We note that the final CY 2014 PFS direct PE input database reflects the refined direct PE inputs that we are adopting on an interim final basis for CY 2014. That database is available under downloads for the CY 2014 PFS final rule with comment period on the CMS website at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html. We also note that the PE RVUs displayed in Addenda B and C reflect the interim final values and policies described in this section. All PE RVUs adopted on an interim final basis for CY 2014 are included in Addendum C and are open for comment in this final rule with comment period.

ii. Common Refinements

Table 29 details our refinements of the AMA RUC's direct PE recommendations at the code-specific level. In this section, we discuss the general nature of some common refinements and the reasons for particular refinements.

(a) Changes in Physician Time

Some direct PE inputs are directly affected by revisions in physician time described in section II.E.3.a. of this final rule with comment period. We note that for many codes, changes in the intraservice portions of the physician time and changes in the number or level of postoperative visits included in the global periods result in corresponding changes to direct PE inputs. We also note that, for a significant number of services, especially diagnostic tests, the procedure time assumptions used in determining direct PE inputs are distinct from, and therefore not dependent on, physician intraservice time assumptions. For these services, we do not make refinements to the direct PE inputs based on changes to estimated physician intraservice times.

Changes in Intraservice Physician Time in the Nonfacility Setting. For most codes valued in the nonfacility setting, a portion of the clinical labor time allocated to the intraservice period reflects minutes assigned for assisting the physician with the procedure. To the extent that we are refining the times associated with the intraservice portion of such procedures, we have adjusted the corresponding intraservice clinical labor minutes in the nonfacility setting.

For equipment associated with the intraservice period in the nonfacility setting, we generally allocate time based on the typical number of minutes a piece of equipment is being used, and therefore, not available for use with another patient during that period. In general, we allocate these minutes based on the description of typical clinical labor activities. To the extent that we are making changes in the clinical labor times associated with the intraservice portion of procedures, we have adjusted the corresponding equipment minutes associated with the codes.

Changes in the Number or Level of Postoperative Office Visits in the Global Period. For codes valued with postservice physician office visits during a global period, most of the clinical labor time allocated to the postservice period reflects a standard number of minutes allocated for each of those visits. To the extent that we are refining the number or level of postoperative visits, we have modified the clinical staff time in the postservice period to reflect the change. For codes valued with postservice physician office visits during a global period, we allocate standard equipment for each of those visits. To

the extent that we are making a change in the number or level of postoperative visits associated with a code, we have adjusted the corresponding equipment minutes. For codes valued with postservice physician office visits during a global period, a certain number of supply items are allocated for each of those office visits. To the extent that we are making a change in the number of postoperative visits, we have adjusted the corresponding supply item quantities associated with the codes. We note that many supply items associated with postservice physician office visits are allocated for each office visit (for example, a minimum multi-specialty visit pack (SA048) in the CY 2014 direct PE input database). For these supply items, the quantities in the direct PE input database should reflect the number of office visits associated with the code's global period. However, some supply items are associated with postservice physician office visits but are only allocated once during the global period because they are typically used during only one of the postservice office visits (for example, pack, post-op incision care (suture) (SA054) in the direct PE input database). For these supply items, the quantities in the direct PE input database reflect that single quantity.

These refinements are reflected in the final CY 2014 PFS direct PE input database and detailed in Table 29.

(b) Equipment Minutes

In general, the equipment time inputs reflect the sum of the times within the intraservice period when a clinician is using the piece of equipment, plus any additional time the piece of equipment is not available for use for another patient due to its use during the designated procedure. While some services include equipment that is typically unavailable during the entire clinical labor service period, certain highly technical pieces of equipment and equipment rooms are less likely to be used by a clinician for all tasks associated with a service, and therefore, are typically available for other patients during the preservice and postservice components of the service period. We adjust those equipment times accordingly. We refer interested stakeholders to our extensive discussion of these policies in the CY 2012 PFS final rule with comment period (76 FR 73182-73183) and in section II.E.2.b. of this final rule with comment period. We are refining the CY 2014 AMA RUC direct PE recommendations to conform

to these equipment time policies. These refinements are reflected in the final CY 2013 PFS direct PE input database and detailed in Table 29.

(c) Moderate Sedation Inputs

In the CY 2012 PFS final rule (76 FR 73043-73049), we finalized a standard package of direct PE inputs for services where moderate sedation is considered inherent in the procedure. We are refining the CY 2014 AMA RUC direct PE recommendations to conform to these policies. These refinements are reflected in the final CY 2013 PFS direct PE input database and detailed in Table 29.

(d) Standard Minutes for Clinical Labor Tasks

In general, the preservice, service period, and postservice clinical labor minutes associated with clinical labor inputs in the direct PE input database reflect the sum of particular tasks described in the information that accompanies the recommended direct PE inputs on "PE worksheets." For most of these described tasks, there are a standardized number of minutes, depending on the type of procedure, its typical setting, its global period, and the other procedures with which it is typically reported. At times, the AMA RUC recommends a number of minutes either greater than or less than the time typically allotted for certain tasks. In those cases, CMS clinical staff reviews the deviations from the standards to assess whether they are clinically appropriate. Where the AMA RUC-recommended exceptions are not accepted, we refine the interim final direct PE inputs to match the standard times for those tasks. In addition, in cases when a service is typically billed with an E/M, we remove the preservice clinical labor tasks so that the inputs are not duplicative and reflect the resource costs of furnishing the typical service.

In some cases the AMA RUC recommendations include additional minutes described by a category called "other clinical activity," or through the addition of clinical labor tasks that are different from those previously included as standard. In these instances, CMS clinical staff reviews the tasks as described in the recommendation to determine whether they are already incorporated into the total number of minutes based on the standard tasks. Additionally, CMS reviews these tasks in the context of the kinds of tasks delineated for other services under the PFS. For those tasks that are duplicative or not separately incorporated for other services, we do not accept those additional clinical labor tasks as direct

inputs. These refinements are reflected in the final CY 2013 PFS direct PE input database and detailed in Table 29.

(e) New Supply and Equipment Items

The AMA RUC generally recommends the use of supply and equipment items that already exist in the direct PE input database for new, revised, and potentially misvalued codes. Some recommendations include supply or equipment items that are not currently in the direct PE input database. In these cases, the AMA RUC has historically recommended a new item be created and has facilitated CMS's pricing of that item by working with the specialty societies to provide sales invoices to us.

We received invoices for several new supply and equipment items for CY 2014. We have accepted the majority of these items and added them to the direct PE input database. However, in many cases we cannot adequately price a newly recommended item due to inadequate information. In some cases, no supporting information regarding the price of the item has been included in the recommendation to create a new item. In other cases, the supporting information does not demonstrate that the item has been purchased at the listed price (for example, price quotes instead of paid invoices). In cases where the information provided allowed us to identify clinically appropriate proxy items, we have used currently existing items as proxies for the newly recommended items. In other cases, we have included the item in the direct PE input database without an associated price. While including the item without an associated price means that the item does not contribute to the calculation of the PE RVU for particular services, it facilitates our ability to incorporate a price once we are able to do so.

(f) Recommended Items that are not Direct PE Inputs

In some cases, the recommended direct PE inputs included items that are not clinical labor, disposable supplies, or medical equipment resources. We have addressed these kinds of recommendations in previous rulemaking and in sections II.E.2.b. and II.B.4.a. of this final rule with comment period. Refinements to adjust for these recommended inputs are reflected in the final CY 2013 PFS direct PE input database and detailed in Table 29.

iii. Code-Specific Refinements

(a) Breast Biopsy (CPT codes 19085, 19086, 19287, and 19288)

The AMA RUC submitted recommended direct PE inputs for CPT codes 19085, 19086, 19287, 19288, including suggestions to create new PE inputs for items called "20MM handpiece – MR," "vacuum line assembly," "introducer localization set (trocar)," and "tissue filter." CMS clinical staff reviewed these recommended items and concluded that each of these items serve redundant clinical purposes with other biopsy supplies already included as direct PE inputs for the codes. Similarly, CMS clinical staff reviewed three newly recommended equipment items described as "breast biopsy software," "breast biopsy device (coil)," and "lateral grid," and determined that these items serve clinical functions to similar items already included in MR room equipment package (EL008). Therefore, we did not create new direct PE inputs for these seven items. These refinements, as well as other applicable standard and common refinements for these codes, are reflected in the final CY 2014 PFS direct PE input database and detailed in Table 29.

(b) Esophagoscopy, Esophagogastroduodenoscopy and Endoscopic Retrograde Cholangiopancreatography (CPT codes 43270, 43229, and 43198)

For CY 2014, the CPT Editorial Panel revised the set of codes that describe esophagoscopy, esophagogastroduodenoscopy (EGD) and endoscopic retrograde cholangiopancreatography (ERCP). These revisions included the addition and deletion of several codes and the development of new guidelines and coding instructions. The AMA RUC provided CMS with recommended direct PE inputs for these services.

For two codes within this family, CPT codes 43270 and 43229, the AMA RUC recommended including the supply item called "kit, probe, radiofrequency, XIi-enhanced RF probe" (SA100) as a proxy for an RF ablation catheter, as well as a new recommended equipment item called "radiofrequency generator (Angiodynamics)." The AMA RUC did not provide additional information regarding what portion of the RF ablation catheter might be reusable. Additionally, the recommendation did not provide information regarding why the supply item SA100 that is priced at \$2,695 would be an appropriate proxy for the RF ablation catheter. The CY 2013 codes that would be used to report these services do not

increase in resource costs without more detail regarding the item for which the recommended input would serve as a proxy. We note that in previous rulemaking (77 FR 69031) we have addressed recommendations for other codes that also suggested using this expensive disposable supply as a proxy input. For these other services, we created a proxy equipment item instead of a proxy supply item, pending the submission of additional information regarding the newly recommended item.

We also note that the AMA RUC recommendation did not include adequate information that would allow us to price the newly recommended item called "radiofrequency generator (Angiodynamics)." To incorporate the best estimate of resource costs for these items for these new codes for CY 2014, we followed the precedents set in previous rulemaking and created a new equipment item to serve as a proxy for the "RF ablation catheter," and used a currently existing radiofrequency generator equipment item (EQ214) as a proxy item pending the submission of additional information regarding these items.

For another new code in the family, CPT code 43198, the AMA RUC recommended including a disposable supply item called "endoscopic biopsy forceps" (SD066). However, additional information included with the recommendation suggested that a reusable biopsy forceps is typically used in furnishing the service. Therefore, we did not incorporate the disposable forceps in the direct PE input database.

These refinements, as well as other applicable standard and common refinements for these codes, are reflected in the final CY 2014 PFS direct PE input database and detailed in Table 29.

(c) Dilation of Esophagus (CPT codes 43450 and 43453)

The AMA RUC recommended direct PE input updates for CTP codes 43450 and 43453. The recommendation included a new item listed as a supply called "esophageal bougies." We note that we did not receive an invoice or additional description of this item and, based on CMS clinical staff clinical review, we believe the functionality of this kind of item can be accomplished through the use of a reusable piece of equipment. Therefore, we created a new equipment item called "esophageal bougies, set, reusable." Once we receive appropriate pricing information regarding the new item, we will update

the price in the direct PE input database. This refinement and other applicable standard and common refinements for these codes are reflected in the final CY 2014 PFS direct PE input database and detailed in Table 29.

(d) MRI of Brain (CPT codes 70551, 70552, and 70553)

The AMA RUC recommended updated direct PE inputs for a series of codes that describe magnetic resonance imaging (MRI) of the brain. We note the AMA RUC recommended that the typical length of time it takes for the MRI technician to acquire images is equal to the time it took in 2002, when the PE inputs for the codes were last evaluated.

When reviewing the direct PE inputs for this code, CMS clinical staff concluded that there should be no significant difference between the assumed time to acquire images for MRI of the brain and MRI of the spine; therefore, we have adjusted the direct PE inputs accordingly. This refinement and other applicable standard and common refinements for these codes are reflected in the final CY 2014 PFS direct PE input database and detailed in Table 29.

(e) Selective Catheter Placement (CPT codes 36245 and 75726)

The AMA RUC submitted new direct PE inputs for CPT code 36245 (Selective catheter placement, arterial system; each first order abdominal, pelvic, or lower extremity artery branch, within a vascular family). We have reviewed the recommended direct PE inputs for this service and made the applicable standard and common refinements which are reflected in the final CY 2014 PFS direct PE input database and detailed in Table 29. However, we note that the review of CPT code 36245 was initiated based on the identification of the code through two misvalued code screens. One of these was the screen that identifies codes reported together at least 75 percent of the time. As the RUC noted in its recommendation, CPT 36245 may be reported with a number of different radiologic supervision and interpretation codes including 75726 (Angiography, visceral, selective or supraselective (with or without flush aortogram), radiological supervision and interpretation). The AMA RUC recommendation stated that, because these code combinations were valued as individual component codes, no potential for duplication of physician work exists. The recommended direct PE inputs for CPT 36245 did not address

whether or not the direct PE inputs for CPT code 75726 should be updated given that it is typically reported with CPT code 36245.

The current direct PE inputs for 75726 include 73 clinical labor minutes for "assist physician in performing procedure." This time matches the precise number of minutes assumed for the same task for CPT code 36245 in the existing direct PE inputs. The AMA RUC has recommended changing the amount of time considered typical for that task from 73 minutes to 45 minutes and we are accepting that change, without refinement, on an interim final basis for CY 2014. Given that these codes are typically reported together and the underlying procedure time assumption used in valuing 75726 is dependent on the assumed times for 36245, we believe it is appropriate to make a corresponding change to 75726 on an interim final basis to reflect the best estimate of resources for these services which are frequently furnished together. This change is reflected in the final CY 2014 PFS direct PE input database and detailed in Table 29.

(g) Respiratory motion management simulation (CPT code 77293)

The AMA RUC submitted direct PE inputs recommendations for CPT code 77293 (Respiratory motion management simulation). Among these was the recommendation to create a new equipment item called "virtual simulation package." However, the information that accompanied the recommendation included a price quote for the new item instead of a copy of paid invoice. We believe that the currently existing item "radiation virtual simulation system" (ER057) will serve as an appropriate proxy for the new item pending our receipt of additional information regarding the newly recommended item. This refinement and other applicable standard and common refinements for these codes are reflected in the final CY 2014 PFS direct PE input database and detailed in Table 29.

(h) Stereotactic Body Radiation Therapy (CPT code 77373)

The AMA RUC recommended updated direct PE inputs for CPT code 77373 (Stereotactic body radiation therapy, treatment delivery, per fraction to 1 or more lesions, including image guidance, entire course not to exceed 5 fractions). We note that we previously established final direct PE inputs for this code in the CY 2013 PFS final rule with comment period (77 FR 68922) in response to direct PE inputs

we proposed in the CY 2013 PFS proposed rule (77 FR 44743). In finalizing the direct PE inputs for this code, we explained that we were including the equipment item called "radiation treatment vault" (ER056) based on public comment, and noting that we had questions regarding whether the item is appropriately categorized as equipment within the established PE methodology. The AMA RUC recommendations did not include the "radiation treatment vault" (ER056) for CPT 77373. Because we intend to address that issue in future rulemaking, we believe that we should continue to include the item as a direct PE input for CY 2014. This refinement and other applicable standard and common refinements for these codes are reflected in the final CY 2014 PFS direct PE input database and detailed in Table 29.

(i) Immunohistochemistry (CPT codes 88342 and 88343 and HCPCS codes G0461 and G0462

The AMA RUC recommended direct PE inputs for revised CPT code 88342 and new CPT code 88343. We direct the reader to section II.E.3 of this final rule with comment period. There, we discuss our decision for CY 2014 to use HCPCS codes G0461 and G0462 for Medicare services instead of reporting the CPT codes describing immunohistochemistry services and to use the AMA RUC recommended values for the CPT codes in establishing interim final values for the HCPCS codes. We based the interim final direct PE inputs for G0461 and G0462 on the recommended inputs for CPT codes 88342 and 88343, therefore the standard and common refinements to the recommended direct PE inputs for these CPT codes are detailed in Table 29 as the inputs for G0461 and G0462. Likewise, the interim final direct PE inputs for G0461 and G0462 appear in the final CY 2014 PFS direct PE input database.

(j) Anogenital Examination with Colposcopic Magnification in Childhood for Suspected Trauma (CPT code 99170)

The AMA RUC recommended updated direct PE inputs for CPT code 99170. As part of that recommendation, the AMA RUC recommended that we create a new clinical labor type called "Child Life Specialist" to be included in the direct PE input database for this particular service. The recommendation also contained additional information that might facilitate the development of an appropriate cost/minute for this new clinical labor type. After reviewing that information, we conclude that the resource costs for the new clinical labor type are very similar to the costs associated with the

existing nurse blend clinical labor type (L037D). Therefore, we have created a new clinical labor category called "Child Life Specialist" (L037E) with a rate per minute crosswalked from the existing labor type L037D.

We also note that the direct PE input recommendation for this code did not conform to the usual format. The PE worksheet included minutes for the new clinical labor type but instead of assigning minutes to specified clinical labor tasks, the worksheet referenced a narrative description of the tasks for the clinical labor type in the preservice, intra-, and postservice periods. This format did not limit our clinical staff from reviewing the recommendation, but it does not allow us to display refinements for particular tasks in Table 29. Instead, the refinements to the recommended aggregate number of minutes for each time component appear in the table along with other applicable standard and common refinements to the recommended direct PE inputs.

TABLE 28: CY 2014 Interim Final Codes with Direct PE Input Recommendations Accepted without Refinement

CPT Code	CPT Code Description
17003	Destruct premalg les 2-14
17311	Mohs 1 stage h/n/hf/g
17312	Mohs addl stage
17313	Mohs 1 stage t/a/l
17314	Mohs addl stage t/a/l
17315	Mohs surg addl block
19081	Bx breast 1st lesion strtctc
19082	Bx breast add lesion strtctc
19083	Bx breast 1st lesion us imag
19084	Bx breast add lesion us imag
19283	Perq dev breast 1st strtctc
19284	Perq dev breast add strtctc
19285	Perq dev breast 1st us imag
23333	Remove shoulder fb deep
23334	Shoulder prosthesis removal
23335	Shoulder prosthesis removal
24160	Remove elbow joint implant

CPT Code	CPT Code Description
24164	Remove radius head implant
27130	Total hip arthroplasty
27236	Treat thigh fracture
27446	Revision of knee joint
27447	Total knee arthroplasty
27466	Lengthening of thigh bone
31239	Nasal/sinus endoscopy surg
31240	Nasal/sinus endoscopy surg
33282	Implant pat-active ht record
33284	Remove pat-active ht record
35301	Rechanneling of artery
37217	Stent placemt retro carotid
37239	Open/perq place stent ea add
43191	Esophagoscopy rigid trnso dx
43192	Esophagoscp rig trnso inject
43193	Esophagoscp rig trnso biopsy
43194	Esophagoscp rig trnso rem fb
43195	Esophagoscopy rigid balloon
43196	Esophagoscp guide wire dilat
43204	Esoph scope w/sclerosis inj
43205	Esophagus endoscopy/ligation
43211	Esophagoscop mucosal resect
43212	Esophagoscop stent placement
43214	Esophagosc dilate balloon 30
43233	Egd balloon dil esoph30 mm/>
43237	Endoscopic us exam esoph
43238	Egd us fine needle bx/aspir
43240	Egd w/transmural drain cyst
43241	Egd tube/cath insertion
43242	Egd us fine needle bx/aspir
43243	Egd injection varices
43244	Egd varices ligation
43246	Egd place gastrostomy tube
43251	Egd remove lesion snare
43253	Egd us transmural injxn/mark
43254	Egd endo mucosal resection
43257	Egd w/thrml txmnt gerd
43259	Egd us exam duodenum/jejunum

CPT Code	CPT Code Description
43260	Ercp w/specimen collection
43261	Endo cholangiopancreatograph
43262	Endo cholangiopancreatograph
43263	Ercp sphincter pressure meas
43264	Ercp remove duct calculi
43265	Ercp lithotripsy calculi
43266	Egd endoscopic stent place
43273	Endoscopic pancreatoscopy
43274	Ercp duct stent placement
43275	Ercp remove forgn body duct
43276	Ercp stent exchange w/dilate
43277	Ercp ea duct/ampulla dilate
43278	Ercp lesion ablate w/dilate
50360	Transplantation of kidney
52356	Cysto/uretero w/lithotripsy
62310	Inject spine cerv/thoracic
62311	Inject spine lumbar/sacral
62318	Inject spine w/cath crv/thrc
62319	Inject spine w/cath lmb/scrl
63047	Remove spine lamina 1 lmbr
63048	Remove spinal lamina add-on
64643	Chemodenery 1 extrem 1-4 ea
64645	Chemodenery 1 extrem 5/> ea
66183	Insert ant drainage device
69210	Remove impacted ear wax uni
77001	Fluoroguide for vein device
77002	Needle localization by xray
77003	Fluoroguide for spine inject
77280	Set radiation therapy field
77285	Set radiation therapy field
77290	Set radiation therapy field
77295	3-d radiotherapy plan
77301	Radiotherapy dose plan imrt
77336	Radiation physics consult
77338	Design mlc device for imrt
77372	Srs linear based
88112	Cytopath cell enhance tech
90839	Psytx crisis initial 60 min

CPT Code	CPT Code Description
90840	Psytx crisis ea addl 30 min
90875	Psychophysiological therapy
91065	Breath hydrogen/methane test
92521	Evaluation of speech fluency
92522	Evaluate speech production
92523	Speech sound lang comprehen
92524	Behavral qualit analys voice
93000	Electrocardiogram complete
93005	Electrocardiogram tracing
93010	Electrocardiogram report
95928	C motor evoked uppr limbs
95929	C motor evoked lwr limbs
96365	Ther/proph/diag iv inf init
96366	Ther/proph/diag iv inf addon
96367	Tx/proph/dg addl seq iv inf
96368	Ther/diag concurrent inf
96413	Chemo iv infusion 1 hr
96415	Chemo iv infusion addl hr
96417	Chemo iv infus each addl seq
98940	Chiropract manj 1-2 regions
98941	Chiropract manj 3-4 regions
98942	Chiropractic manj 5 regions
98943	Chiropract manj xtrspinl 1/>

TABLE 29: CY 2014 Interim Final Codes with Direct PE Input Recommendations Accepted with Refinements

HCPCS Code	HCPCS Code Descrip- tion	Input Code	Input Code Description	Non- Fac/ Fac	Labor Activity (if applicable)	RUC Recommen dation or Current Value (min or qty)	CMS Refine ment (min or qty)	Comment
10030	Guide cathet fluid drainage	EF018	stretcher	NF		120	0	Non- standard input for Moderate Sedation
		EF027	table, instrument, mobile	NF		159	152	Standard input for Moderate Sedation

HCPCS Code	HCPCS Code Descrip- tion	Input Code	Input Code Description	Non- Fac/ Fac	Labor Activity (if applicable)	RUC Recommen dation or Current Value (min or qty)	CMS Refine ment (min or qty)	Comment
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		159	152	Standard input for Moderate Sedation
		EQ032	IV infusion pump	NF		159	152	Standard input for Moderate Sedation
		L037D	RN/LPN/MTA	NF	Circulating throughout procedure (25%)	8	7	Conforms to proportion ate allocation of intraservic e time among clinical labor types
17000	Destruct premalg lesion	ED004	camera, digital (6 mexapixel)	NF		22	13	Refined equipment time to conform to changes in clinical labor time
		EF031	table, power	NF		46	40	Refined equipment time to conform to changes in clinical labor time
		EQ093	cryosurgery equipment (for liquid nitrogen)	NF		22	13	Refined equipment time to conform to changes in clinical labor time
		EQ168	light, exam	NF		46	40	Refined equipment time to conform to changes in clinical labor time

HCPCS Code	HCPCS Code Descrip- tion	Input Code	Input Code Description	Non- Fac/ Fac	Labor Activity (if applicable)	RUC Recommen dation or Current Value (min or qty)	CMS Refine ment (min or qty)	Comment
		SA048	pack, minimum multi-specialty visit	NF		1	2	CMS clinical review
		SA048	pack, minimum multi-specialty visit	F		0	1	CMS clinical review
		ED004	camera, digital (6 mexapixel)	NF		41	30	Refined equipment time to conform to changes in clinical labor time
17004	Destroy premal lesions 15/>	EQ093	cryosurgery equipment (for liquid nitrogen)	NF		41	30	Refined equipment time to conform to changes in clinical labor time
		SA048	pack, minimum multi-specialty visit	NF		1	2	CMS clinical review
		SA048	pack, minimum multi-specialty visit	F		0	1	CMS clinical review
19085	Bx breast 1st lesion mr imag	S	20MM handpiece - MR	NF		1	0	CMS clinical review; functionali ty of items redundant with other direct PE inputs
		S	vacuum line assembly	NF		1	0	CMS clinical review; functionali ty of items redundant with other direct PE inputs

HCPCS Code	HCPCS Code Descrip- tion	Input Code	Input Code Description	Non- Fac/ Fac	Labor Activity (if applicable)	RUC Recommen dation or Current Value (min or qty)	CMS Refine ment (min or qty)	Comment
		S	introducer localization set (trocar)	NF		1	0	CMS clinical review; functionali ty of items redundant with other direct PE inputs
		S	tissue filter	NF		1	0	CMS clinical review; functionali ty of items redundant with other direct PE inputs
		Е	breast biopsy software	NF		54	0	CMS clinical review; functionali ty of items redundant with other direct PE inputs
		E	breast biopsy device (coil)	NF		54	0	CMS clinical review; functionali ty of items redundant with other direct PE inputs
		Е	lateral grid	NF		54	0	CMS clinical review; functionali ty of items redundant with other direct PE inputs

HCPCS Code	HCPCS Code Descrip- tion	Input Code	Input Code Description	Non- Fac/ Fac	Labor Activity (if applicable)	RUC Recommen dation or Current Value (min or qty)	CMS Refine ment (min or qty)	Comment
19086	Bx breast add lesion mr imag	S	20MM handpiece - MR	NF		1	0	CMS clinical review; functionali ty of items redundant with other direct PE inputs
		S	vacuum line assembly	NF		1	0	CMS clinical review; functionali ty of items redundant with other direct PE inputs
		S	introducer localization set (trocar)	NF		1	0	CMS clinical review; functionali ty of items redundant with other direct PE inputs
		S	tissue filter	NF		1	0	CMS clinical review; functionali ty of items redundant with other direct PE inputs
		E	breast biopsy software	NF		43	0	CMS clinical review; functionali ty of items redundant with other direct PE inputs

HCPCS Code	HCPCS Code Descrip- tion	Input Code	Input Code Description	Non- Fac/ Fac	Labor Activity (if applicable)	RUC Recommen dation or Current Value (min or qty)	CMS Refine ment (min or qty)	Comment
		E	breast biopsy device (coil)	NF		43	0	CMS clinical review; functionali ty of items redundant with other direct PE inputs
		Е	lateral grid	NF		43	0	CMS clinical review; functionali ty of items redundant with other direct PE inputs
		ED025	film processor, wet	NF		9	5	Refined equipment time to conform to changes in clinical labor time
	Perq	ER029	film alternator (motorized film viewbox)	NF		9	5	CMS clinical review
1 14/X 1 1	device breast 1st imag	L043A	Mammography Technologist	NF	Process images, complete data sheet, present images and data to the interpreting physician	9	5	CMS clinical review
19282	Perq device breast ea imag	ED025	film processor, wet	NF		9	5	Refined equipment time to conform to changes in clinical labor time

HCPCS Code	HCPCS Code Descrip- tion	Input Code	Input Code Description	Non- Fac/ Fac	Labor Activity (if applicable)	RUC Recommen dation or Current Value (min or qty)	CMS Refine ment (min or qty)	Comment
		ER029	film alternator (motorized film viewbox)	NF		9	5	Refined equipment time to conform to changes in clinical labor time
		L043A	Mammography Technologist	NF	Other Clinical Activity (Service)	9	5	CMS clinical review
19286	Perq dev breast add us imag	L043A	Mammography Technologist	NF	Assist physician in performing procedure	19	14	Conformin g to physician time
19287	Perq dev breast 1st mr guide	S	20MM handpiece - MR	NF		1	0	CMS clinical review; functionali ty of items redundant with other direct PE inputs
		S	vacuum line assembly	NF		1	0	CMS clinical review; functionali ty of items redundant with other direct PE inputs
		S	introducer localization set (trocar)	NF		1	0	CMS clinical review; functionali ty of items redundant with other direct PE inputs

HCPCS Code	HCPCS Code Descrip- tion	Input Code	Input Code Description	Non- Fac/ Fac	Labor Activity (if applicable)	RUC Recommen dation or Current Value (min or qty)	CMS Refine ment (min or qty)	Comment
		S	tissue filter	NF		1	0	CMS clinical review; functionali ty of items redundant with other direct PE inputs
		E	breast biopsy software	NF		46	0	CMS clinical review; functionali ty of items redundant with other direct PE inputs
		E	breast biopsy device (coil)	NF		46	0	CMS clinical review; functionali ty of items redundant with other direct PE inputs
		Е	lateral grid	NF		46	0	CMS clinical review; functionali ty of items redundant with other direct PE inputs
19288	Perq dev breast add mr guide	S	20MM handpiece - MR	NF		1	0	CMS clinical review; functionali ty of items redundant with other direct PE inputs

HCPCS Code	HCPCS Code Descrip- tion	Input Code	Input Code Description	Non- Fac/ Fac	Labor Activity (if applicable)	RUC Recommen dation or Current Value (min or qty)	CMS Refine ment (min or qty)	Comment
		S	vacuum line assembly	NF		1	0	CMS clinical review; functionali ty of items redundant with other direct PE inputs
		S	introducer localization set (trocar)	NF		1	0	CMS clinical review; functionali ty of items redundant with other direct PE inputs
		S	tissue filter	NF		1	0	CMS clinical review; functionali ty of items redundant with other direct PE inputs
		E	breast biopsy software	NF		35	0	CMS clinical review; functionali ty of items redundant with other direct PE inputs
		Е	breast biopsy device (coil)	NF		35	0	CMS clinical review; functionali ty of items redundant with other direct PE inputs

HCPCS Code	HCPCS Code Descrip- tion	Input Code	Input Code Description	Non- Fac/ Fac	Labor Activity (if applicable)	RUC Recommen dation or Current Value (min or qty)	CMS Refine ment (min or qty)	Comment
		E	lateral grid	NF		35	0	CMS clinical review; functionali ty of items redundant with other direct PE inputs
		EF031	table, power	F		90	63	Refined equipment time to conform to changes in clinical labor time
23333	Remove shoulder fb deep	EQ168	light, exam	F		90	63	Refined equipment time to conform to changes in clinical labor time
		L037D	RN/LPN/MTA	F	Total Office Visit Time	90	63	Conformin g to physician time
		SA048	pack, minimum multi-specialty visit	F		3	2	Conformin g to physician time
		L037D	RN/LPN/MTA	F	Post Service Period	99	108	Conformin g to physician time
27130	Total hip arthropla sty	EF031	table, power	F		99	108	Refined equipment time to conform to changes in clinical labor time
27447	Total knee arthropla sty	L037D	RN/LPN/MTA	F	Post Service Period	99	108	Conformin g to physician time

HCPCS Code	HCPCS Code Descrip- tion	Input Code	Input Code Description	Non- Fac/ Fac	Labor Activity (if applicable)	RUC Recommen dation or Current Value (min or qty)	CMS Refine ment (min or qty)	Comment
		EF031	table, power	F		99	108	Refined equipment time to conform to changes in clinical labor time
31237	Nasal/sin us endoscop y surg	L037D	RN/LPN/MTA	NF	Monitor pt. following service/che ck tubes, monitors, drains	15	5	CMS clinical review
31238	Nasal/sin us endoscop y surg	L037D	RN/LPN/MTA	NF	Monitor pt. following service/che ck tubes, monitors, drains	15	5	CMS clinical review
33366	Treath replace aortic valve	L037D	RN/LPN/MTA	F	Coordinate pre-surgery services	40	20	CMS clinical review; refinement reflects standard preservice times
36245	Ins cath abd/l-ext art 1st	EF018	stretcher	NF		240	0	Non- standard input for Moderate Sedation
37236	Open/per q place stent 1st	EF018	stretcher	NF		240	0	Non- standard input for Moderate Sedation
		EF027	table, instrument, mobile	NF		347	332	Standard input for Moderate Sedation

HCPCS Code	HCPCS Code Descrip- tion	Input Code	Input Code Description	Non- Fac/ Fac	Labor Activity (if applicable)	RUC Recommen dation or Current Value (min or qty)	CMS Refine ment (min or qty)	Comment
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		347	332	Standard input for Moderate Sedation
		EQ032	IV infusion pump	NF		347	332	Standard input for Moderate Sedation
		S	Balloon expandable	NF		1	0	CMS clinical review; input already exists
		SD152	catheter, balloon, PTA	NF		0	1	CMS clinical review; input already exists
27227	Open/per	S	Balloon expandable	NF		1	0	CMS clinical review; input already exists
37237	stent ea add	SD152	catheter, balloon, PTA	NF		0	1	CMS clinical review; input already exists
37238	Open/per q place stent same	EF018	stretcher	NF		180	0	Non- standard input for Moderate Sedation
		EF027	table, instrument, mobile	NF		257	302	Standard input for Moderate Sedation
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		257	302	Standard input for Moderate Sedation

HCPCS Code	HCPCS Code Descrip- tion	Input Code	Input Code Description	Non- Fac/ Fac	Labor Activity (if applicable)	RUC Recommen dation or Current Value (min or qty)	CMS Refine ment (min or qty)	Comment
		EQ032	IV infusion pump	NF		257	302	Standard input for Moderate Sedation
		EF018	stretcher	NF		180	0	Non- standard input for Moderate Sedation
		EF027	table, instrument, mobile	NF		287	272	Standard input for Moderate Sedation
	Vasc	EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		287	272	Standard input for Moderate Sedation
37241	embolize /occlude venous	EQ032	IV infusion pump	NF		287	272	Standard input for Moderate Sedation
		L037D	RN/LPN/MTA	NF	Circulating throughout procedure (25%)	23	22	Conforms to proportion ate allocation of intraservic e time among clinical labor types
37242	Vasc embolize /occlude artery	EF018	stretcher	NF		240	0	Non- standard input for Moderate Sedation
		EF027	table, instrument, mobile	NF		357	342	Standard input for Moderate Sedation
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		357	342	Standard input for Moderate Sedation

HCPCS Code	HCPCS Code Descrip- tion	Input Code	Input Code Description	Non- Fac/ Fac	Labor Activity (if applicable)	RUC Recommen dation or Current Value (min or qty)	CMS Refine ment (min or qty)	Comment
		EQ032	IV infusion pump	NF		357	342	Standard input for Moderate Sedation
		EF018	stretcher	NF		240	0	Non- standard input for Moderate Sedation
37243	Vasc embolize	EF027	table, instrument, mobile	NF		377	362	Standard input for Moderate Sedation
	/occlude organ	EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		377	362	Standard input for Moderate Sedation
		EQ032	IV infusion pump	NF		377	362	Standard input for Moderate Sedation
37244	Vasc embolize /occlude bleed	EF018	stretcher	NF		240	0	Non- standard input for Moderate Sedation
		EF027	table, instrument, mobile	NF		347	332	Standard input for Moderate Sedation
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		347	332	Standard input for Moderate Sedation
		EQ032	IV infusion pump	NF		347	332	Standard input for Moderate Sedation

HCPCS Code	HCPCS Code Descrip- tion	Input Code	Input Code Description	Non- Fac/ Fac	Labor Activity (if applicable)	RUC Recommen dation or Current Value (min or qty)	CMS Refine ment (min or qty)	Comment
		L037D	RN/LPN/MTA	NF	Circulating throughout procedure (25%)	23	22	Conforms to proportion ate allocation of intraservic e time among clinical labor types
43197	Esophag oscopy flex dx brush	ED036	video printer, color (Sony medical grade)	NF		15	39	Refined equipment time to conform to established policies for technical equipment
		EF008	chair with headrest, exam, reclining	NF		15	39	Refined equipment time to conform to established policies for technical equipment
		EF015	mayo stand	NF		15	39	Refined equipment time to conform to established policies for technical equipment
		EQ170	light, fiberoptic headlight w- source	NF		15	39	Refined equipment time to conform to established policies for technical equipment

HCPCS Code	HCPCS Code Descrip- tion	Input Code	Input Code Description	Non- Fac/ Fac	Labor Activity (if applicable)	RUC Recommen dation or Current Value (min or qty)	CMS Refine ment (min or qty)	Comment
		EQ234	suction and pressure cabinet, ENT (SMR)	NF		15	39	Refined equipment time to conform to established policies for technical equipment
		ER095	transnasal esophagoscope 80K series	NF		15	66	Refined equipment time to conform to established policies for technical equipment
		ES026	video add-on camera system w-monitor (endoscopy)	NF		15	39	Refined equipment time to conform to established policies for technical equipment
		ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart)	NF		15	39	Refined equipment time to conform to established policies for technical equipment
		L026A	Medical/Technic al Assistant	NF	Clean Surgical Instrument Package	10	0	Standardiz ed time input; surgical instrument package not included
43198	Esophag osc flex trnsn biopsy	ED036	video printer, color (Sony medical grade)	NF		20	46	Refined equipment time to conform to established policies for technical equipment

HCPCS Code	HCPCS Code Descrip- tion	Input Code	Input Code Description	Non- Fac/ Fac	Labor Activity (if applicable)	RUC Recommen dation or Current Value (min or qty)	CMS Refine ment (min or qty)	Comment
		EF008	chair with headrest, exam, reclining	NF		20	46	Refined equipment time to conform to established policies for technical equipment
		EF015	mayo stand	NF		20	46	Refined equipment time to conform to established policies for technical equipment
		EQ170	light, fiberoptic headlight w- source	NF		20	46	Refined equipment time to conform to established policies for technical equipment
		EQ234	suction and pressure cabinet, ENT (SMR)	NF		20	46	Refined equipment time to conform to established policies for technical equipment
		ER095	transnasal esophagoscope 80K series	NF		20	73	Refined equipment time to conform to established policies for technical equipment
		ES026	video add-on camera system w-monitor (endoscopy)	NF		20	46	Refined equipment time to conform to established policies for technical equipment

HCPCS Code	HCPCS Code Descrip- tion	Input Code	Input Code Description	Non- Fac/ Fac	Labor Activity (if applicable)	RUC Recommen dation or Current Value (min or qty)	CMS Refine ment (min or qty)	Comment
		ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart)	NF		20	46	Refined equipment time to conform to established policies for technical equipment
		L026A	Medical/Technic al Assistant	NF	Clean Surgical Instrument Package	10	0	Standardiz ed time input
		SD066	endoscopic biopsy forceps	NF		1	0	CMS clinical review
43200	Esophag oscopy flexible brush	EF018	stretcher	NF		73	0	Non- standard input for Moderate Sedation
		EF027	table, instrument, mobile	NF		29	77	Standard input for Moderate Sedation
		EF031	table, power	NF		29	43	Refined equipment time to conform to established policies for technical equipment
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		52	77	Standard input for Moderate Sedation
		EQ032	IV infusion pump	NF		52	77	Standard input for Moderate Sedation

HCPCS Code	HCPCS Code Descrip- tion	Input Code	Input Code Description	Non- Fac/ Fac	Labor Activity (if applicable)	RUC Recommen dation or Current Value (min or qty)	CMS Refine ment (min or qty)	Comment
		EQ235	suction machine (Gomco)	NF		29	43	Refined equipment time to conform to established policies for technical equipment
		ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart)	NF		29	43	Refined equipment time to conform to established policies for technical equipment
		ES034	videoscope, gastroscopy	NF		59	70	Refined equipment time to conform to established policies for technical equipment
		SD009	canister, suction	NF		2	1	CMS clinical review
43201	Esoph scope w/submu cous inj	EF018	stretcher	NF		76	0	Non- standard input for Moderate Sedation
		EF027	table, instrument, mobile	NF		32	80	Standard input for Moderate Sedation
		EF031	table, power	NF		32	46	Refined equipment time to conform to changes in clinical labor time
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		55	80	Standard input for Moderate Sedation

HCPCS Code	HCPCS Code Descrip- tion	Input Code	Input Code Description	Non- Fac/ Fac	Labor Activity (if applicable)	RUC Recommen dation or Current Value (min or qty)	CMS Refine ment (min or qty)	Comment
		EQ032	IV infusion pump	NF		55	80	Standard input for Moderate Sedation
		EQ235	suction machine (Gomco)	NF		32	46	Refined equipment time to conform to changes in clinical labor time
		ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart)	NF		32	46	Refined equipment time to conform to changes in clinical labor time
		ES034	videoscope, gastroscopy	NF		62	73	Refined equipment time to conform to changes in clinical labor time
		L037D	RN/LPN/MTA	NF	Assist physician in performing procedure	18	15	Conformin g to physician time
		L051A	RN	NF	Monitor patient during Moderate Sedation	18	15	Conformin g to physician time
		SC079	needle, micropigmentati on (tattoo)	NF		1	0	CMS clinical review
		SD009	canister, suction	NF		2	1	CMS clinical review
		SL035	cup, biopsy- specimen non- sterile 4oz	NF		1	0	CMS clinical review

HCPCS Code	HCPCS Code Descrip- tion	Input Code	Input Code Description	Non- Fac/ Fac	Labor Activity (if applicable)	RUC Recommen dation or Current Value (min or qty)	CMS Refine ment (min or qty)	Comment
43202	Esophag oscopy flex biopsy	EF018	stretcher	NF		78	0	Non- standard input for Moderate Sedation
		EF027	table, instrument, mobile	NF		34	82	Standard input for Moderate Sedation
		EF031	table, power	NF		34	48	Refined equipment time to conform to changes in clinical labor time
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		57	82	Standard input for Moderate Sedation
		EQ032	IV infusion pump	NF		57	82	Standard input for Moderate Sedation
		EQ235	suction machine (Gomco)	NF		34	48	Refined equipment time to conform to changes in clinical labor time
		ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart)	NF		34	48	Refined equipment time to conform to changes in clinical labor time
		ES034	videoscope, gastroscopy	NF		64	75	Refined equipment time to conform to changes in clinical labor time

HCPCS Code	HCPCS Code Descrip- tion	Input Code	Input Code Description	Non- Fac/ Fac	Labor Activity (if applicable)	RUC Recommen dation or Current Value (min or qty)	CMS Refine ment (min or qty)	Comment
		L037D	RN/LPN/MTA	NF	Assist physician in performing procedure	20	15	Conformin g to physician time
		L051A	RN	NF	Monitor patient during Moderate Sedation	20	15	Conformin g to physician time
		SD009	canister, suction	NF		2	1	CMS clinical review
43206	Esoph optical endomicr oscopy	EF018	stretcher	NF		91	0	Non- standard input for Moderate Sedation
		EF027	table, instrument, mobile	NF		47	92	Standard input for Moderate Sedation
		EF031	table, power	NF		47	61	Refined equipment time to conform to established policies for technical equipment
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		70	92	Standard input for Moderate Sedation
		EQ032	IV infusion pump	NF		70	92	Standard input for Moderate Sedation
		EQ235	suction machine (Gomco)	NF		47	61	Refined equipment time to conform to established policies for technical equipment

HCPCS Code	HCPCS Code Descrip- tion	Input Code	Input Code Description	Non- Fac/ Fac	Labor Activity (if applicable)	RUC Recommen dation or Current Value (min or qty)	CMS Refine ment (min or qty)	Comment
		EQ355	optical endomicroscope processor unit system	NF		77	61	Refined equipment time to conform to established policies for technical equipment
		ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart)	NF		47	61	Refined equipment time to conform to established policies for technical equipment
		ES034	videoscope, gastroscopy	NF		77	88	Refined equipment time to conform to established policies for technical equipment
		SD009	canister, suction	NF		2	1	CMS clinical review
43213	Esophag oscopy retro balloon	EF018	stretcher	NF		103	0	Non- standard input for Moderate Sedation
		EF027	table, instrument, mobile	NF		59	107	Standard input for Moderate Sedation
		EF031	table, power	NF		59	73	Refined equipment time to conform to established policies for technical equipment
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		82	107	Standard input for Moderate Sedation

HCPCS Code	HCPCS Code Descrip- tion	Input Code	Input Code Description	Non- Fac/ Fac	Labor Activity (if applicable)	RUC Recommen dation or Current Value (min or qty)	CMS Refine ment (min or qty)	Comment
		EQ032	IV infusion pump	NF		82	107	Standard input for Moderate Sedation
		EQ235	suction machine (Gomco)	NF		59	73	Refined equipment time to conform to established policies for technical equipment
		ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart)	NF		59	73	Refined equipment time to conform to established policies for technical equipment
		ES034	videoscope, gastroscopy	NF		89	100	Refined equipment time to conform to established policies for technical equipment
43215	Esophag oscopy flex remove fb	EF018	stretcher	NF		78	0	Non- standard input for Moderate Sedation
		EF027	table, instrument, mobile	NF		34	82	Standard input for Moderate Sedation
		EF031	table, power	NF		34	48	Refined equipment time to conform to established policies for technical equipment

HCPCS Code	HCPCS Code Descrip- tion	Input Code	Input Code Description	Non- Fac/ Fac	Labor Activity (if applicable)	RUC Recommen dation or Current Value (min or qty)	CMS Refine ment (min or qty)	Comment
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		57	82	Standard input for Moderate Sedation
		EQ032	IV infusion pump	NF		57	82	Standard input for Moderate Sedation
		EQ235	suction machine (Gomco)	NF		34	48	Refined equipment time to conform to established policies for technical equipment
		ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart)	NF		34	48	Refined equipment time to conform to established policies for technical equipment
		ES034	videoscope, gastroscopy	NF		64	75	Refined equipment time to conform to established policies for technical equipment
		SD009	canister, suction	NF		2	1	CMS clinical review
43216	Esophag oscopy lesion removal	EF018	stretcher	NF		80	0	Non- standard input for Moderate Sedation
		EF027	table, instrument, mobile	NF		36	84	Standard input for Moderate Sedation

HCPCS Code	HCPCS Code Descrip- tion	Input Code	Input Code Description	Non- Fac/ Fac	Labor Activity (if applicable)	RUC Recommen dation or Current Value (min or qty)	CMS Refine ment (min or qty)	Comment
		EF031	table, power	NF		36	50	Refined equipment time to conform to established policies for technical equipment
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		59	84	Standard input for Moderate Sedation
		EQ032	IV infusion pump	NF		59	84	Standard input for Moderate Sedation
		EQ113	electrosurgical generator, gastrocautery	NF		36	50	Refined equipment time to conform to established policies for technical equipment
		EQ235	suction machine (Gomco)	NF		36	50	Refined equipment time to conform to established policies for technical equipment
		ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart)	NF		36	50	Refined equipment time to conform to established policies for technical equipment
		ES034	videoscope, gastroscopy	NF		66	77	Refined equipment time to conform to established policies for technical equipment

HCPCS Code	HCPCS Code Descrip- tion	Input Code	Input Code Description	Non- Fac/ Fac	Labor Activity (if applicable)	RUC Recommen dation or Current Value (min or qty)	CMS Refine ment (min or qty)	Comment
		SD009	canister, suction	NF		2	1	CMS clinical review
43217	Esophag oscopy snare les remv	EF018	stretcher	NF		88	0	Non- standard input for Moderate Sedation
		EF027	table, instrument, mobile	NF		44	92	Standard input for Moderate Sedation
		EF031	table, power	NF		44	58	Refined equipment time to conform to established policies for technical equipment
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		67	92	Standard input for Moderate Sedation
		EQ032	IV infusion pump	NF		67	92	Standard input for Moderate Sedation
		EQ113	electrosurgical generator, gastrocautery	NF		44	58	Refined equipment time to conform to established policies for technical equipment
		EQ235	suction machine (Gomco)	NF		44	58	Refined equipment time to conform to established policies for technical equipment

HCPCS Code	HCPCS Code Descrip- tion	Input Code	Input Code Description	Non- Fac/ Fac	Labor Activity (if applicable)	RUC Recommen dation or Current Value (min or qty)	CMS Refine ment (min or qty)	Comment
		ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart)	NF		44	58	Refined equipment time to conform to established policies for technical equipment
		ES034	videoscope, gastroscopy	NF		74	85	Refined equipment time to conform to established policies for technical equipment
		SD009	canister, suction	NF		2	1	CMS clinical review
43220	Esophag oscopy balloon <30mm	EF018	stretcher	NF		78	0	Non- standard input for Moderate Sedation
		EF027	table, instrument, mobile	NF		34	82	Standard input for Moderate Sedation
		EF031	table, power	NF		34	48	Refined equipment time to conform to established policies for technical equipment
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		57	82	Standard input for Moderate Sedation
		EQ032	IV infusion pump	NF		57	82	Standard input for Moderate Sedation

HCPCS Code	HCPCS Code Descrip- tion	Input Code	Input Code Description	Non- Fac/ Fac	Labor Activity (if applicable)	RUC Recommen dation or Current Value (min or qty)	CMS Refine ment (min or qty)	Comment
		EQ235	suction machine (Gomco)	NF		34	48	Refined equipment time to conform to established policies for technical equipment
		ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart)	NF		34	48	Refined equipment time to conform to established policies for technical equipment
		ES034	videoscope, gastroscopy	NF		64	75	Refined equipment time to conform to established policies for technical equipment
		SD009	canister, suction	NF		2	1	CMS clinical review
		SD019	catheter, balloon, ureteral-GI (strictures)	NF		SD205	SD019	Supply proxy change due to CMS clinical review
		SD090	guidewire, STIFF	NF		1	0	CMS clinical review
		SL035	cup, biopsy- specimen non- sterile 4oz	NF		1	0	CMS clinical review
43226	Esoph endoscop y dilation	EF018	stretcher	NF		83	0	Non- standard input for Moderate Sedation
		EF027	table, instrument, mobile	NF		39	87	Standard input for Moderate Sedation

HCPCS Code	HCPCS Code Descrip- tion	Input Code	Input Code Description	Non- Fac/ Fac	Labor Activity (if applicable)	RUC Recommen dation or Current Value (min or qty)	CMS Refine ment (min or qty)	Comment
		EF031	table, power	NF		39	53	Refined equipment time to conform to established policies for technical equipment
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		62	87	Standard input for Moderate Sedation
		EQ032	IV infusion pump	NF		62	87	Standard input for Moderate Sedation
		EQ235	suction machine (Gomco)	NF		39	53	Refined equipment time to conform to established policies for technical equipment
		ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart)	NF		39	53	Refined equipment time to conform to established policies for technical equipment
		ES034	videoscope, gastroscopy	NF		69	80	Refined equipment time to conform to established policies for technical equipment
		L037D	RN/LPN/MTA	NF	Clean Surgical Instrument Package	0	10	Standardiz ed time input
		SD009	canister, suction	NF		2	1	CMS clinical review

HCPCS Code	HCPCS Code Descrip- tion	Input Code	Input Code Description	Non- Fac/ Fac	Labor Activity (if applicable)	RUC Recommen dation or Current Value (min or qty)	CMS Refine ment (min or qty)	Comment
		SL035	cup, biopsy- specimen non- sterile 4oz	NF		1	0	CMS clinical review
43227	Esophag oscopy control bleed	EF018	stretcher	NF		88	0	Non- standard input for Moderate Sedation
		EF027	table, instrument, mobile	NF		44	92	Standard input for Moderate Sedation
		EF031	table, power	NF		44	58	Refined equipment time to conform to established policies for technical equipment
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		67	92	Standard input for Moderate Sedation
		EQ032	IV infusion pump	NF		67	92	Standard input for Moderate Sedation
		EQ113	electrosurgical generator, gastrocautery	NF		44	58	Refined equipment time to conform to established policies for technical equipment
		EQ235	suction machine (Gomco)	NF		44	58	Refined equipment time to conform to established policies for technical equipment

HCPCS Code	HCPCS Code Descrip- tion	Input Code	Input Code Description	Non- Fac/ Fac	Labor Activity (if applicable)	RUC Recommen dation or Current Value (min or qty)	CMS Refine ment (min or qty)	Comment
		ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart)	NF		44	58	Refined equipment time to conform to established policies for technical equipment
		ES034	videoscope, gastroscopy	NF		74	85	Refined equipment time to conform to established policies for technical equipment
		SD009	canister, suction	NF		2	1	CMS clinical review
43229	Esophag oscopy lesion ablate	EF018	stretcher	NF		103	0	Non- standard input for Moderate Sedation
		EF027	table, instrument, mobile	NF		59	107	Standard input for Moderate Sedation
		EF031	table, power	NF		59	73	Refined equipment time to conform to established policies for technical equipment
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		82	107	Standard input for Moderate Sedation
		EQ032	IV infusion pump	NF		82	107	Standard input for Moderate Sedation

HCPCS Code	HCPCS Code Descrip- tion	Input Code	Input Code Description	Non- Fac/ Fac	Labor Activity (if applicable)	RUC Recommen dation or Current Value (min or qty)	CMS Refine ment (min or qty)	Comment
		EQ113	electrosurgical generator, gastrocautery	NF		59	73	Refined equipment time to conform to established policies for technical equipment
		EQ214	radiofrequency generator (NEURO)	NF		59	73	CMS clinical review; see discussion in section II.D.3.b. of this final rule
		EQ235	suction machine (Gomco)	NF		59	73	Refined equipment time to conform to established policies for technical equipment
		EQ356	kit, probe, radiofrequency, XIi-enhanced RF probe (proxy for catheter, RF ablation, endoscopic)	NF		0	73	CMS clinical review; see discussion in section II.D.3.b. of this final rule
		ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart)	NF		59	73	Refined equipment time to conform to established policies for technical equipment
		ES034	videoscope, gastroscopy	NF		89	100	Refined equipment time to conform to established policies for technical equipment

HCPCS Code	HCPCS Code Descrip- tion	Input Code	Input Code Description	Non- Fac/ Fac	Labor Activity (if applicable)	RUC Recommen dation or Current Value (min or qty)	CMS Refine ment (min or qty)	Comment
		SA100	kit, probe, radiofrequency, XIi-enhanced RF probe	NF		1	0	CMS clinical review
43231	Esophag oscop ultrasoun d exam	EF018	stretcher	NF		103	0	Non- standard input for Moderate Sedation
		EF027	table, instrument, mobile	NF		59	107	Standard input for Moderate Sedation
		EF031	table, power	NF		59	73	Refined equipment time to conform to changes in clinical labor time
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		82	107	Standard input for Moderate Sedation
		EQ032	IV infusion pump	NF		82	107	Standard input for Moderate Sedation
		EQ235	suction machine (Gomco)	NF		59	73	Refined equipment time to conform to changes in clinical labor time
		ER094	endoscopic ultrasound processor	NF		59	73	Refined equipment time to conform to changes in clinical labor time

HCPCS Code	HCPCS Code Descrip- tion	Input Code	Input Code Description	Non- Fac/ Fac	Labor Activity (if applicable)	RUC Recommen dation or Current Value (min or qty)	CMS Refine ment (min or qty)	Comment
		ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart)	NF		59	73	Refined equipment time to conform to changes in clinical labor time
		ES038	videoscope, endoscopic ultrasound	NF		89	100	Refined equipment time to conform to changes in clinical labor time
		L037D	RN/LPN/MTA	NF	Assist physician in performing procedure	45	30	Conformin g to physician time
		L051A	RN	NF	Monitor patient during Moderate Sedation	45	30	Conformin g to physician time
		SD009	canister, suction	NF		2	1	CMS clinical review
		SL035	cup, biopsy- specimen non- sterile 4oz	NF		1	0	CMS clinical review
43232	Esophag oscopy w/us needle bx	EF018	stretcher	NF		118	0	Non- standard input for Moderate Sedation
		EF027	table, instrument, mobile	NF		74	122	Standard input for Moderate Sedation
		EF031	table, power	NF		74	88	Refined equipment time to conform to changes in clinical labor time

HCPCS Code	HCPCS Code Descrip- tion	Input Code	Input Code Description	Non- Fac/ Fac	Labor Activity (if applicable)	RUC Recommen dation or Current Value (min or qty)	CMS Refine ment (min or qty)	Comment
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		97	122	Standard input for Moderate Sedation
		EQ032	IV infusion pump	NF		97	122	Standard input for Moderate Sedation
		EQ235	suction machine (Gomco)	NF		74	88	Refined equipment time to conform to changes in clinical labor time
		ER094	endoscopic ultrasound processor	NF		74	88	Refined equipment time to conform to changes in clinical labor time
		ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart)	NF		74	88	Refined equipment time to conform to changes in clinical labor time
		ES038	videoscope, endoscopic ultrasound	NF		104	115	Refined equipment time to conform to changes in clinical labor time
		L037D	RN/LPN/MTA	NF	Assist physician in performing procedure	60	45	Conformin g to physician time
		L051A	RN	NF	Monitor patient during Moderate Sedation	60	45	Conformin g to physician time

HCPCS Code	HCPCS Code Descrip- tion	Input Code	Input Code Description	Non- Fac/ Fac	Labor Activity (if applicable)	RUC Recommen dation or Current Value (min or qty)	CMS Refine ment (min or qty)	Comment
		SD009	canister, suction	NF		2	1	CMS clinical review
43235	Egd diagnosti c brush wash	EF018	stretcher	NF		73	0	Non- standard input for Moderate Sedation
		EF027	table, instrument, mobile	NF		29	77	Standard input for Moderate Sedation
		EF031	table, power	NF		29	43	Refined equipment time to conform to established policies for technical equipment
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		52	77	Standard input for Moderate Sedation
		EQ032	IV infusion pump	NF		52	77	Standard input for Moderate Sedation
		EQ235	suction machine (Gomco)	NF		29	43	Refined equipment time to conform to established policies for technical equipment
		ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart)	NF		29	43	Refined equipment time to conform to established policies for technical equipment

HCPCS Code	HCPCS Code Descrip- tion	Input Code	Input Code Description	Non- Fac/ Fac	Labor Activity (if applicable)	RUC Recommen dation or Current Value (min or qty)	CMS Refine ment (min or qty)	Comment
		ES034	videoscope, gastroscopy	NF		59	70	Refined equipment time to conform to established policies for technical equipment
		SD009	canister, suction	NF		2	1	CMS clinical review
43236	Uppr gi scope w/submu c inj	EF018	stretcher	NF		78	0	Non- standard input for Moderate Sedation
		EF027	table, instrument, mobile	NF		34	82	Standard input for Moderate Sedation
		EF031	table, power	NF		34	48	Refined equipment time to conform to established policies for technical equipment
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		57	82	Standard input for Moderate Sedation
		EQ032	IV infusion pump	NF		57	82	Standard input for Moderate Sedation
		EQ235	suction machine (Gomco)	NF		34	48	Refined equipment time to conform to established policies for technical equipment

HCPCS Code	HCPCS Code Descrip- tion	Input Code	Input Code Description	Non- Fac/ Fac	Labor Activity (if applicable)	RUC Recommen dation or Current Value (min or qty)	CMS Refine ment (min or qty)	Comment
		ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart)	NF		34	48	Refined equipment time to conform to established policies for technical equipment
		ES034	videoscope, gastroscopy	NF		64	75	Refined equipment time to conform to established policies for technical equipment
		SD009	canister, suction	NF		2	1	CMS clinical review
43239	Egd biopsy single/m ultiple	EF018	stretcher	NF		73	0	Non- standard input for Moderate Sedation
		EF027	table, instrument, mobile	NF		29	77	Standard input for Moderate Sedation
		EF031	table, power	NF		29	43	Refined equipment time to conform to established policies for technical equipment
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		52	77	Standard input for Moderate Sedation
		EQ032	IV infusion pump	NF		52	77	Standard input for Moderate Sedation

HCPCS Code	HCPCS Code Descrip- tion	Input Code	Input Code Description	Non- Fac/ Fac	Labor Activity (if applicable)	RUC Recommen dation or Current Value (min or qty)	CMS Refine ment (min or qty)	Comment
		EQ235	suction machine (Gomco)	NF		29	43	Refined equipment time to conform to established policies for technical equipment
		ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart)	NF		29	43	Refined equipment time to conform to established policies for technical equipment
		ES034	videoscope, gastroscopy	NF		59	70	Refined equipment time to conform to established policies for technical equipment
		SD009	canister, suction	NF		2	1	CMS clinical review
43245	Egd dilate stricture	EF018	stretcher	NF		81	0	Non- standard input for Moderate Sedation
		EF027	table, instrument, mobile	NF		37	85	Standard input for Moderate Sedation
		EF031	table, power	NF		37	51	Refined equipment time to conform to established policies for technical equipment
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		60	85	Standard input for Moderate Sedation

HCPCS Code	HCPCS Code Descrip- tion	Input Code	Input Code Description	Non- Fac/ Fac	Labor Activity (if applicable)	RUC Recommen dation or Current Value (min or qty)	CMS Refine ment (min or qty)	Comment
		EQ032	IV infusion pump	NF		60	85	Standard input for Moderate Sedation
		EQ235	suction machine (Gomco)	NF		37	51	Refined equipment time to conform to established policies for technical equipment
		ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart)	NF		37	51	Refined equipment time to conform to established policies for technical equipment
		ES034	videoscope, gastroscopy	NF		67	78	Refined equipment time to conform to established policies for technical equipment
		SD009	canister, suction	NF		2	1	CMS clinical review
43247	Egd remove foreign body	EF018	stretcher	NF		88	0	Non- standard input for Moderate Sedation
		EF027	table, instrument, mobile	NF		44	92	Standard input for Moderate Sedation
		EF031	table, power	NF		44	58	Refined equipment time to conform to established policies for technical equipment

HCPCS Code	HCPCS Code Descrip- tion	Input Code	Input Code Description	Non- Fac/ Fac	Labor Activity (if applicable)	RUC Recommen dation or Current Value (min or qty)	CMS Refine ment (min or qty)	Comment
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		67	92	Standard input for Moderate Sedation
		EQ032	IV infusion pump	NF		67	92	Standard input for Moderate Sedation
		EQ235	suction machine (Gomco)	NF		44	58	Refined equipment time to conform to established policies for technical equipment
		ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart)	NF		44	58	Refined equipment time to conform to established policies for technical equipment
		ES034	videoscope, gastroscopy	NF		74	85	Refined equipment time to conform to established policies for technical equipment
		SD009	canister, suction	NF		2	1	CMS clinical review
43248	Egd guide wire insertion	EF018	stretcher	NF		78	0	Non- standard input for Moderate Sedation
		EF027	table, instrument, mobile	NF		34	82	Standard input for Moderate Sedation

HCPCS Code	HCPCS Code Descrip- tion	Input Code	Input Code Description	Non- Fac/ Fac	Labor Activity (if applicable)	RUC Recommen dation or Current Value (min or qty)	CMS Refine ment (min or qty)	Comment
		EF031	table, power	NF		34	48	Refined equipment time to conform to established policies for technical equipment
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		57	82	Standard input for Moderate Sedation
		EQ032	IV infusion pump	NF		57	82	Standard input for Moderate Sedation
		EQ137	instrument pack, basic (\$500- \$1499)	NF		64	55	Refined equipment time to conform to established policies for technical equipment
		EQ235	suction machine (Gomco)	NF		34	48	Refined equipment time to conform to established policies for technical equipment
		ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart)	NF		34	48	Refined equipment time to conform to established policies for technical equipment
		ES034	videoscope, gastroscopy	NF		64	75	Refined equipment time to conform to established policies for technical equipment

HCPCS Code	HCPCS Code Descrip- tion	Input Code	Input Code Description	Non- Fac/ Fac	Labor Activity (if applicable)	RUC Recommen dation or Current Value (min or qty)	CMS Refine ment (min or qty)	Comment
		SD009	canister, suction	NF		2	1	CMS clinical review
43249	Esoph egd dilation <30 mm	EF018	stretcher	NF		78	0	Non- standard input for Moderate Sedation
		EF027	table, instrument, mobile	NF		34	82	Standard input for Moderate Sedation
		EF031	table, power	NF		34	48	Refined equipment time to conform to established policies for technical equipment
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		57	82	Standard input for Moderate Sedation
		EQ032	IV infusion pump	NF		57	82	Standard input for Moderate Sedation
		EQ235	suction machine (Gomco)	NF		34	48	Refined equipment time to conform to established policies for technical equipment
		ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart)	NF		34	48	Refined equipment time to conform to established policies for technical equipment

HCPCS Code	HCPCS Code Descrip- tion	Input Code	Input Code Description	Non- Fac/ Fac	Labor Activity (if applicable)	RUC Recommen dation or Current Value (min or qty)	CMS Refine ment (min or qty)	Comment
		ES034	videoscope, gastroscopy	NF		64	75	Refined equipment time to conform to established policies for technical equipment
		SD009	canister, suction	NF		2	1	CMS clinical review
		SD090	guidewire, STIFF	NF		1	0	CMS clinical review
43250	Egd cautery tumor polyp	EF018	stretcher	NF		78	0	Non- standard input for Moderate Sedation
		EF027	table, instrument, mobile	NF		34	82	Standard input for Moderate Sedation
		EF031	table, power	NF		34	48	Refined equipment time to conform to established policies for technical equipment
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		57	82	Standard input for Moderate Sedation
		EQ032	IV infusion pump	NF		57	82	Standard input for Moderate Sedation
		EQ113	electrosurgical generator, gastrocautery	NF		34	48	Refined equipment time to conform to established policies for technical equipment

HCPCS Code	HCPCS Code Descrip- tion	Input Code	Input Code Description	Non- Fac/ Fac	Labor Activity (if applicable)	RUC Recommen dation or Current Value (min or qty)	CMS Refine ment (min or qty)	Comment
		EQ235	suction machine (Gomco)	NF		34	48	Refined equipment time to conform to established policies for technical equipment
		ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart)	NF		34	48	Refined equipment time to conform to established policies for technical equipment
		ES034	videoscope, gastroscopy	NF		64	75	Refined equipment time to conform to established policies for technical equipment
		SD009	canister, suction	NF		2	1	CMS clinical review
43251	Egd remove lesion snare	EF018	stretcher	NF		78	0	Non- standard input for Moderate Sedation
		EF027	table, instrument, mobile	NF		34	82	Standard input for Moderate Sedation
		EF031	table, power	NF		34	48	Refined equipment time to conform to established policies for technical equipment
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		57	82	Standard input for Moderate Sedation

HCPCS Code	HCPCS Code Descrip- tion	Input Code	Input Code Description	Non- Fac/ Fac	Labor Activity (if applicable)	RUC Recommen dation or Current Value (min or qty)	CMS Refine ment (min or qty)	Comment
		EQ032	IV infusion pump	NF		57	82	Standard input for Moderate Sedation
		EQ113	electrosurgical generator, gastrocautery	NF		34	48	Refined equipment time to conform to established policies for technical equipment
		EQ235	suction machine (Gomco)	NF		34	48	Refined equipment time to conform to established policies for technical equipment
		ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart)	NF		34	48	Refined equipment time to conform to established policies for technical equipment
		ES034	videoscope, gastroscopy	NF		64	75	Refined equipment time to conform to established policies for technical equipment
		SD009	canister, suction	NF		2	1	CMS clinical review
43252	Egd optical endomicr oscopy	EF018	stretcher	NF		78	0	Non- standard input for Moderate Sedation
		EF027	table, instrument, mobile	NF		34	92	Standard input for Moderate Sedation

HCPCS Code	HCPCS Code Descrip- tion	Input Code	Input Code Description	Non- Fac/ Fac	Labor Activity (if applicable)	RUC Recommen dation or Current Value (min or qty)	CMS Refine ment (min or qty)	Comment
		EF031	table, power	NF		34	61	Refined equipment time to conform to established policies for technical equipment
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		70	92	Standard input for Moderate Sedation
		EQ032	IV infusion pump	NF		57	92	Standard input for Moderate Sedation
		EQ235	suction machine (Gomco)	NF		34	61	Refined equipment time to conform to established policies for technical equipment
		EQ355	optical endomicroscope processor unit system	NF		77	61	Refined equipment time to conform to established policies for technical equipment
		ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart)	NF		34	61	Refined equipment time to conform to established policies for technical equipment
		ES034	videoscope, gastroscopy	NF		64	88	Refined equipment time to conform to established policies for technical equipment

HCPCS Code	HCPCS Code Descrip- tion	Input Code	Input Code Description	Non- Fac/ Fac	Labor Activity (if applicable)	RUC Recommen dation or Current Value (min or qty)	CMS Refine ment (min or qty)	Comment
		SD009	canister, suction	NF		2	1	CMS clinical review
43255	Egd control bleeding any	EF018	stretcher	NF		88	0	Non- standard input for Moderate Sedation
		EF027	table, instrument, mobile	NF		44	92	Standard input for Moderate Sedation
		EF031	table, power	NF		44	58	Refined equipment time to conform to established policies for technical equipment
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		67	92	Standard input for Moderate Sedation
		EQ032	IV infusion pump	NF		67	92	Standard input for Moderate Sedation
		EQ113	electrosurgical generator, gastrocautery	NF		44	58	Refined equipment time to conform to established policies for technical equipment
		EQ235	suction machine (Gomco)	NF		44	58	Refined equipment time to conform to established policies for technical equipment

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		ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart)	NF		44	58	Refined equipment time to conform to established policies for technical equipment
		ES034	videoscope, gastroscopy	NF		74	85	Refined equipment time to conform to established policies for technical equipment
		SD009	canister, suction	NF		2	1	CMS clinical review
43270	Egd lesion ablation	EF018	stretcher	NF		103	0	Non- standard input for Moderate Sedation
		EF027	table, instrument, mobile	NF		82	107	Standard input for Moderate Sedation
		EF031	table, power	NF		59	73	Refined equipment time to conform to established policies for technical equipment
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		82	107	Standard input for Moderate Sedation
		EQ032	IV infusion pump	NF		82	107	Standard input for Moderate Sedation

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		EQ113	electrosurgical generator, gastrocautery	NF		59	73	Refined equipment time to conform to established policies for technical equipment
		EQ214	radiofrequency generator (NEURO)	NF		59	73	CMS clinical review; see discussion in section II.D.3.b. of this final rule
		EQ235	suction machine (Gomco)	NF		59	73	Refined equipment time to conform to established policies for technical equipment
		EQ356	kit, probe, radiofrequency, XIi-enhanced RF probe (proxy for catheter, RF ablation, endoscopic)	NF		0	73	CMS clinical review; see discussion in section II.D.3.b. of this final rule
		ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart)	NF		59	73	Refined equipment time to conform to established policies for technical equipment
		ES034	videoscope, gastroscopy	NF		89	100	Refined equipment time to conform to established policies for technical equipment

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		SA100	kit, probe, radiofrequency, XIi-enhanced RF probe	NF		1	0	CMS clinical review
		SD009	canister, suction	NF		2	1	CMS clinical review
		SD090	guidewire, STIFF	NF		1	0	CMS clinical review
43450	Dilate esophagu s 1/mult pass	E	Mobile stand, Vital Signs Monitor	NF		47	0	Non- standard input for Moderate Sedation
		EF014	light, surgical	NF		24	36	Refined equipment time to conform to established policies for technical equipment
		EF018	stretcher	NF		51	0	Non- standard input for Moderate Sedation
		EF027	table, instrument, mobile	NF		24	77	Standard input for Moderate Sedation
		EF031	table, power	NF		24	36	Refined equipment time to conform to established policies for technical equipment
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		47	77	Standard input for Moderate Sedation
		EQ032	IV infusion pump	NF		47	77	Standard input for Moderate Sedation

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		EQ235	suction machine (Gomco)	NF		24	36	Refined equipment time to conform to established policies for technical equipment
		EQ357	esophageal bougies, set, reusable	NF		0	36	CMS clinical review; see discussion in section II.D.3.b. of this final rule
		ES005	endoscope disinfector, rigid or fiberoptic, w- cart	NF		15	0	CMS clinical review
43453	Dilate esophagu s	Е	Mobile stand, Vital Signs Monitor	NF		57	0	CMS clinical review
	-	EF014	light, surgical	NF		34	46	Refined equipment time to conform to changes in clinical labor time
		EF018	stretcher	NF		61	0	Non- standard input for Moderate Sedation
		EF027	table, instrument, mobile	NF		34	87	Standard input for Moderate Sedation
		EF031	table, power	NF		34	46	Refined equipment time to conform to changes in clinical labor time

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		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		57	87	Standard input for Moderate Sedation
		EQ032	IV infusion pump	NF		57	87	Standard input for Moderate Sedation
		EQ235	suction machine (Gomco)	NF		34	46	Refined equipment time to conform to changes in clinical labor time
		ES005	endoscope disinfector, rigid or fiberoptic, w- cart	NF		15	0	CMS clinical review; an endoscope is not included
		L037D	RN/LPN/MTA	NF	Assist physician in performing procedure	25	20	Conformin g to physician time
		L051A	RN	NF	Monitor patient during Moderate Sedation	25	20	Conformin g to physician time
49405	Image cath fluid colxn visc	EF018	stretcher	NF		120	0	Non- standard input for Moderate Sedation
		EF027	table, instrument, mobile	NF		169	162	Standard input for Moderate Sedation
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		169	162	Standard input for Moderate Sedation

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		EQ032	IV infusion pump	NF		169	162	Standard input for Moderate Sedation
		EF018	stretcher	NF		120	0	Non- standard input for Moderate Sedation
49406	Image cath fluid	EF027	table, instrument, mobile	NF		169	162	Standard input for Moderate Sedation
13.100	peri/retro	EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		169	162	Standard input for Moderate Sedation
		EQ032	IV infusion pump	NF		169	162	Standard input for Moderate Sedation
		EF018	stretcher	NF		120	0	Non- standard input for Moderate Sedation
49407	Image cath fluid	EF027	table, instrument, mobile	NF		174	167	Standard input for Moderate Sedation
	trns/vgnl	EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		174	167	Standard input for Moderate Sedation
		EQ032	IV infusion pump	NF		174	167	Standard input for Moderate Sedation
63650	Implant neuroele ctrodes	EF018	stretcher	NF		10	15	Refined equipment time to conform to established policies for technical equipment

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		EF024	table, fluoroscopy	NF		60	84	Refined equipment time to conform to established policies for technical equipment
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		60	84	Refined equipment time to conform to established policies for technical equipment
		ER031	fluoroscopic system, mobile C-Arm	NF		60	69	Refined equipment time to conform to established policies for technical equipment
		L037D	RN/LPN/MTA	NF	Clean Surgical Instrument Package	15	0	Standardiz ed time input
		SA043	pack, cleaning, surgical instruments	NF		1	0	CMS clinical review
64616	Chemode nerv musc neck dyston	EF023	table, exam	NF		28	24	Refined equipment time to conform to changes in clinical labor time
		L037D	RN/LPN/MTA	NF	Other Clinical Activity: Complete botox log	3	0	CMS clinical review

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		L037D	RN/LPN/MTA	NF	Assist physician in performing procedure	7	5	Conformin g to physician time
64617	Chemode ner	EF023	table, exam	NF		30	33	Refined equipment time to conform to changes in clinical labor time
04017	64617 muscle larynx emg	EQ024	EMG-NCV-EP system, 8 channel	NF		30	33	Refined equipment time to conform to changes in clinical labor time
64642	Chemode nerv 1	EF023	table, exam	NF		44	38	Refined equipment time to conform to changes in clinical labor time
04042	extremity 1-4	L037D	RN/LPN/MTA	NF	Other Clinical Activity: Complete botox log	3	0	CMS clinical review
64644	Chemode nerv 1 extrem	EF023	table, exam	NF		49	43	Refined equipment time to conform to established policies for technical equipment
	5/> mus	L037D	RN/LPN/MTA	NF	Other Clinical Activity: Complete botox log	3	0	CMS clinical review

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64646	Chemode nerv trunk	EF023	table, exam	NF		44	38	Refined equipment time to conform to established policies for technical equipment
	trunk musc 1-5	L037D	RN/LPN/MTA	NF	Other Clinical Activity: Complete botox log	3	0	CMS clinical review
64647	Chemode nerv trunk	EF023	table, exam	NF		49	43	Refined equipment time to conform to established policies for technical equipment
	musc 6/>	L037D	RN/LPN/MTA	NF	Other Clinical Activity: Complete botox log	3	0	CMS clinical review
67914	Repair eyelid defect	EF015	mayo stand	NF		31	20	Refined equipment time to conform to established policies for technical equipment
		EL006	lane, screening (oph)	NF		121	110	Refined equipment time to conform to established policies for technical equipment

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		EQ114	electrosurgical generator, up to 120 watts	NF		31	20	Refined equipment time to conform to established policies for technical equipment
		EQ138	instrument pack, medium (\$1500 and up)	NF		43	20	Refined equipment time to conform to established policies for technical equipment
		EQ176	loupes, standard, up to 3.5x	NF		31	20	Refined equipment time to conform to established policies for technical equipment
		L038A	COMT/COT/RN /CST	NF	Clean Surgical Instrument Package	15	10	Standardiz ed time input
		SC027	needle, 18-19g, filter	NF		SB034	SC027	Supply/Eq uipment code correction
		SC057	syringe 5-6ml	NF		SK057	SC057	Supply/Eq uipment code correction
67915	Repair eyelid defect	EF015	mayo stand	NF		21	10	Refined equipment time to conform to established policies for technical equipment

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		EL006	lane, screening (oph)	NF		71	64	Refined equipment time to conform to established policies for technical equipment
		EQ114	electrosurgical generator, up to 120 watts	NF		21	10	Refined equipment time to conform to established policies for technical equipment
		EQ176	loupes, standard, up to 3.5x	NF		21	10	Refined equipment time to conform to established policies for technical equipment
		SB027	gown, staff, impervious	NF		SB034	SB027	Supply/Eq uipment code correction
		SC057	syringe 5-6ml	NF		SK057	SC057	Supply/Eq uipment code correction
(701)	Repair	SB027	gown, staff, impervious	NF		SB034	SB027	Supply/Eq uipment code correction
67916	eyelid defect	SC057	syringe 5-6ml	NF		SK057	SC057	Supply/Eq uipment code correction
(7017	Repair	SB027	gown, staff, impervious	NF		SB034	SB027	Supply/Eq uipment code correction
0/91/	67917 eyelid defect	SC057	syringe 5-6ml	NF		SK057	SC057	Supply/Eq uipment code correction

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(7021	Repair	SB027	gown, staff, impervious	NF		SB034	SB027	Supply/Eq uipment code correction
67921 eyelid defect	defect	SC057	syringe 5-6ml	NF		SK057	SC057	Supply/Eq uipment code correction
67922	Repair	SB027	gown, staff, impervious	NF		SB034	SB027	Supply/Eq uipment code correction
07922	eyelid defect	SC057	syringe 5-6ml	NF		SK057	SC057	Supply/Eq uipment code correction
67923	Repair eyelid	SB027	gown, staff, impervious	NF		SB034	SB027	Supply/Eq uipment code correction
07923	defect	SC057	syringe 5-6ml	NF		SK057	SC057	Supply/Eq uipment code correction
(7024	Repair	SB027	gown, staff, impervious	NF		SB034	SB027	Supply/Eq uipment code correction
67924	eyelid defect	SC057	syringe 5-6ml	NF		SK057	SC057	Supply/Eq uipment code correction
70450	Ct head/brai n w/o dye	ED024	film processor, dry, laser	NF		15	4	Refined equipment time to conform to established policies for technical equipment
		EL007	room, CT	NF		26	17	Refined equipment time to conform to established policies for technical equipment

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		ER029	film alternator (motorized film viewbox)	NF		15	4	Refined equipment time to conform to established policies for technical equipment
		ED024	film processor, dry, laser	NF		15	4	Refined equipment time to conform to established policies for technical equipment
70460	Ct head/brai n w/dye	EL007	room, CT	NF		34	24	Refined equipment time to conform to established policies for technical equipment
		ER029	film alternator (motorized film viewbox)	NF		15	4	Refined equipment time to conform to established policies for technical equipment
70470	Ct head/brai n w/o & w/dye	ED024	film processor, dry, laser	NF		15	6	Refined equipment time to conform to established policies for technical equipment
		EL007	room, CT	NF		42	30	Refined equipment time to conform to established policies for technical equipment

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		ER029	film alternator (motorized film viewbox)	NF		15	6	Refined equipment time to conform to established policies for technical equipment
70551	Mri brain stem w/o dye	EL008	room, MRI	NF		33	31	Refined equipment time to conform to established policies for technical equipment

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		L047A	MRI Technologist	NF	Other Clinical Activity: Retrieve prior appropriate imaging exams and hang for MD review, verify orders, review the chart to incorporate relevant clinical information and confirm contrast protocol with interpreting MD	8	3	CMS clinical review
		L047A	MRI Technologist	NF	Assist physician in performing procedure	30	20	CMS clinical review

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		L047A	MRI Technologist	NF	Other Clinical Activity: Escort patient from exam room due to magnetic sensitivity	2	0	CMS clinical review
70552	Mri brain stem w/dye	EL008	room, MRI	NF		47	45	Refined equipment time to conform to established policies for technical equipment

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		L047A	MRI Technologist	NF	Other Clinical Activity: Retrieve prior appropriate imaging exams and hang for MD review, verify orders, review the chart to incorporate relevant clinical information and confirm contrast protocol with interpreting MD	8	5	CMS clinical review
		L047A	MRI Technologist	NF	Obtain vital signs	0	3	CMS clinical review
		L047A	MRI Technologist	NF	Provide preservice education/o btain consent	9	7	CMS clinical review

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		L047A	MRI Technologist	NF	Other Clinical Activity: Escort patient from exam room due to magnetic sensitivity	2	0	CMS clinical review
		SG053	gauze, sterile 2in x 2in	NF		1	0	CMS clinical review
		SG089	tape, phix strips (for nasal catheter)	NF		6	0	CMS clinical review
		SJ043	povidone swabsticks (3 pack uou)	NF		1	0	CMS clinical review
		SJ053	swab-pad, alcohol	NF		1	0	CMS clinical review
70553	Mri brain stem w/o & w/dye	EL008	room, MRI	NF		57	53	Refined equipment time to conform to established policies for technical equipment

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		L047A	MRI Technologist	NF	Other Clinical Activity: Retrieve prior appropriate imaging exams and hang for MD review, verify orders, review the chart to incorporate relevant clinical information and confirm contrast protocol with interpreting MD	8	5	CMS clinical review
		L047A	MRI Technologist	NF	Obtain vital signs	0	3	CMS clinical review
		L047A	MRI Technologist	NF	Provide preservice education/o btain consent	9	7	CMS clinical review

HCPCS Code	HCPCS Code Descrip- tion	Input Code	Input Code Description	Non- Fac/ Fac	Labor Activity (if applicable)	RUC Recommen dation or Current Value (min or qty)	CMS Refine ment (min or qty)	Comment
		L047A	MRI Technologist	NF	Assist physician in performing procedure	40	38	CMS clinical review
		L047A	MRI Technologist	NF	Other Clinical Activity: Escort patient from exam room due to magnetic sensitivity	2	0	CMS clinical review
		SG053	gauze, sterile 2in x 2in	NF		1	0	CMS clinical review
		SG089	tape, phix strips (for nasal catheter)	NF		6	0	CMS clinical review
		SJ043	povidone swabsticks (3 pack uou)	NF		1	0	CMS clinical review
		SJ053	swab-pad, alcohol	NF		1	0	CMS clinical review
72141	Mri neck spine w/o dye	L047A	MRI Technologist	NF	Other Clinical Activity: Escort patient from exam room due to magnetic sensitivity	2	0	CMS clinical review

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72142	Mri neck spine w/dye	L047A	MRI Technologist	NF	Other Clinical Activity: Escort patient from exam room due to magnetic sensitivity	2	0	CMS clinical review
72146	Mri chest spine w/o dye	L047A	MRI Technologist	NF	Other Clinical Activity: Escort patient from exam room due to magnetic sensitivity	2	0	CMS clinical review
72147	Mri chest spine w/dye	L047A	MRI Technologist	NF	Other Clinical Activity: Escort patient from exam room due to magnetic sensitivity	2	0	CMS clinical review

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72148	Mri lumbar spine w/o dye	L047A	MRI Technologist	NF	Other Clinical Activity: Escort patient from exam room due to magnetic sensitivity	2	0	CMS clinical review
72149	Mri lumbar spine w/dye	L047A	MRI Technologist	NF	Other Clinical Activity: Escort patient from exam room due to magnetic sensitivity	2	0	CMS clinical review
72156	Mri neck spine w/o & w/dye	L047A	MRI Technologist	NF	Other Clinical Activity: Escort patient from exam room due to magnetic sensitivity	2	0	CMS clinical review

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72157	Mri chest spine w/o & w/dye	L047A	MRI Technologist	NF	Other Clinical Activity: Escort patient from exam room due to magnetic sensitivity	2	0	CMS clinical review
72158	Mri lumbar spine w/o & w/dye	L047A	MRI Technologist	NF	Other Clinical Activity: Escort patient from exam room due to magnetic sensitivity	2	0	CMS clinical review
74174	Ct angio abd&pel v w/o&w/d ye	L046A	CT Technologist	NF	Other Clinical Activity: Process films, hang films and review study with interpreting MD prior to patient discharge	25	20	CMS clinical review
75726	Artery x- rays abdomen	L041A	Angio Technician	NF	Assist physician in performing procedure	73	45	CMS clinical review

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		E	Virtual Simulation Package	NF		27	0	CMS clinical review
77280	Set radiation therapy field	ER057	radiation virtual simulation system	NF		0	27	CMS clinical review; inadequate informatio n to price new items; existing item used as a proxy
		E	Virtual Simulation Package	NF		43	0	CMS clinical review
77285	Set radiation therapy field	ER057	radiation virtual simulation system	NF		0	43	cMS clinical review; inadequate informatio n to price new items; existing item used as a proxy
		Е	Virtual Simulation Package	NF		50	0	CMS clinical review
77290	Set radiation therapy field	ER057	radiation virtual simulation system	NF		0	50	CMS clinical review; inadequate informatio n to price new items; existing item used as a proxy
77293	Respirato r motion mgmt	Е	Virtual Simulation Package	NF		40	0	CMS clinical review
	simul	E	4D Simulation Package	NF		40	0	CMS clinical review

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		ER057	radiation virtual simulation system	NF		0	40	CMS clinical review; inadequate informatio n to price new items; existing item used as a proxy
		EQ211	pulse oximeter w-printer	NF		104	86	Refined equipment time to conform to established policies for technical equipment
77373	Sbrt delivery	ER056	radiation treatment vault	NF		0	86	See discussion in section II.D.3.b. of this final rule
		ER083	SRS system, SBRT, six systems, average	NF		104	86	Refined equipment time to conform to established policies for technical equipment
77600	Hyperthe rmia treatment	EF015	mayo stand	NF		123	105	Refined equipment time to conform to established policies for technical equipment
		ER035	hyperthermia system, ultrasound, external	NF		123	105	Refined equipment time to conform to established policies for technical equipment

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		L037D	RN/LPN/MTA	NF	Clean Scope	10	0	CMS clinical review; catheters included are disposable supplies and time is already included for cleaning equipment
77785	Hdr brachytx 1 channel	Е	Emergency service container-safety kit	NF		46	0	Indirect practice expense
		EF021	table, brachytherapy treatment	NF		46	42	Refined equipment time to conform to established policies for technical equipment
		EQ292	Applicator Base Plate	NF		46	42	Refined equipment time to conform to established policies for technical equipment
		ER003	HDR Afterload System, Nucletron - Oldelft	NF		46	42	Refined equipment time to conform to established policies for technical equipment

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		ER028	electrometer, PC-based, dual channel	NF		46	42	Refined equipment time to conform to established policies for technical equipment
		ER054	radiation survey meter	NF		46	42	Refined equipment time to conform to established policies for technical equipment
		ER060	source, 10 Ci Ir 192	NF		46	42	Refined equipment time to conform to established policies for technical equipment
		ER062	stirrups (for brachytherapy table)	NF		46	42	Refined equipment time to conform to established policies for technical equipment
		ER073	Area Radiation Monitor	NF		46	42	Refined equipment time to conform to established policies for technical equipment
77786	Hdr brachytx 2-12 channel	Е	Emergency service container-safety kit	NF		100	0	Indirect practice expense

HCPCS Code	HCPCS Code Descrip- tion	Input Code	Input Code Description	Non- Fac/ Fac	Labor Activity (if applicable)	RUC Recommen dation or Current Value (min or qty)	CMS Refine ment (min or qty)	Comment
		EF021	table, brachytherapy treatment	NF		100	86	Refined equipment time to conform to established policies for technical equipment
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		100	86	Refined equipment time to conform to established policies for technical equipment
		EQ292	Applicator Base Plate	NF		100	86	Refined equipment time to conform to established policies for technical equipment
		ER003	HDR Afterload System, Nucletron - Oldelft	NF		100	86	Refined equipment time to conform to established policies for technical equipment
		ER028	electrometer, PC-based, dual channel	NF		100	86	Refined equipment time to conform to established policies for technical equipment
		ER054	radiation survey meter	NF		100	86	Refined equipment time to conform to established policies for technical equipment

HCPCS Code	HCPCS Code Descrip- tion	Input Code	Input Code Description	Non- Fac/ Fac	Labor Activity (if applicable)	RUC Recommen dation or Current Value (min or qty)	CMS Refine ment (min or qty)	Comment
		ER060	source, 10 Ci Ir 192	NF		100	86	Refined equipment time to conform to established policies for technical equipment
		ER073	Area Radiation Monitor	NF		100	86	Refined equipment time to conform to established policies for technical equipment
77787	Hdr brachytx over 12 chan	E	Emergency service container-safety kit	NF		162	0	Indirect practice expense
		EF021	table, brachytherapy treatment	NF		162	137	Refined equipment time to conform to established policies for technical equipment
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		162	137	Refined equipment time to conform to established policies for technical equipment
		EQ292	Applicator Base Plate	NF		162	137	Refined equipment time to conform to established policies for technical equipment

HCPCS Code	HCPCS Code Descrip- tion	Input Code	Input Code Description	Non- Fac/ Fac	Labor Activity (if applicable)	RUC Recommen dation or Current Value (min or qty)	CMS Refine ment (min or qty)	Comment
		ER003	HDR Afterload System, Nucletron - Oldelft	NF		162	137	Refined equipment time to conform to established policies for technical equipment
		ER028	electrometer, PC-based, dual channel	NF		162	137	Refined equipment time to conform to established policies for technical equipment
		ER054	radiation survey meter	NF		162	137	Refined equipment time to conform to established policies for technical equipment
		ER060	source, 10 Ci Ir 192	NF		162	137	Refined equipment time to conform to established policies for technical equipment
		ER062	stirrups (for brachytherapy table)	NF		162	137	Refined equipment time to conform to established policies for technical equipment
		ER073	Area Radiation Monitor	NF		162	137	Refined equipment time to conform to established policies for technical equipment

HCPCS Code	HCPCS Code Descrip- tion	Input Code	Input Code Description	Non- Fac/ Fac	Labor Activity (if applicable)	RUC Recommen dation or Current Value (min or qty)	CMS Refine ment (min or qty)	Comment
88112	Cytopath cell enhance tech	Е	Laboratory Information System with maintenance contract	NF		2	0	Included in equipment cost per minute calculation
		Е	Copath System Software	NF		2	0	Indirect practice expense
		L035A	Lab Tech/Histotechn ologist	NF	Order, restock, and distribute specimen containers with requisition forms.	0.5	0	CMS clinical review
		L045A	Cytotechnologist	NF	Perform screening function (where applicable)	8	0	CMS clinical review
		L045A	Cytotechnologist	NF	A. Confirm patient ID, organize work, verify and review history	2	0	CMS clinical review

HCPCS Code	HCPCS Code Descrip- tion	Input Code	Input Code Description	Non- Fac/ Fac	Labor Activity (if applicable)	RUC Recommen dation or Current Value (min or qty)	CMS Refine ment (min or qty)	Comment
		L045A	Cytotechnologist	NF	B: Enter screening diagnosis in laboratory information system, complete workload recording logs, manage any relevant utilization review/qual ity assurance activities and regulatory compliance documentat ion and assemble and deliver slides with paperwork to pathologist	2	0	CMS clinical review
		S	Courier transportation costs	NF		2.02	0	Indirect practice expense
		S	Specimen, solvent, and formalin disposal cost	NF		0.18	0	Indirect practice expense

HCPCS Code	HCPCS Code Descrip- tion	Input Code	Input Code Description	Non- Fac/ Fac	Labor Activity (if applicable)	RUC Recommen dation or Current Value (min or qty)	CMS Refine ment (min or qty)	Comment	
		ED021	computer, desktop, w- monitor	NF		68	51	Refined equipment time to conform to established policies for technical equipment	
93880	Extracra	Extracra nial bilat	ED034	video SVHS VCR (medical grade)	NF		68	0	CMS clinical review; functionali ty of items redundant with other direct PE inputs
75000	study	ED036	video printer, color (Sony medical grade)	NF		10	0	CMS clinical review; functionali ty of items redundant with other direct PE inputs	
		EL016	room, ultrasound, vascular	NF		68	51	Refined equipment time to conform to established policies for technical equipment	
93882	Extracra nial uni/ltd study	ED021	computer, desktop, w- monitor	NF		44	29	Refined equipment time to conform to established policies for technical equipment	

HCPCS Code	HCPCS Code Descrip- tion	Input Code	Input Code Description	Non- Fac/ Fac	Labor Activity (if applicable)	RUC Recommen dation or Current Value (min or qty)	CMS Refine ment (min or qty)	Comment
		ED034	video SVHS VCR (medical grade)	NF		44	0	CMS clinical review; functionali ty of items redundant with other direct PE inputs
		ED036	video printer, color (Sony medical grade)	NF		10	0	CMS clinical review; functionali ty of items redundant with other direct PE inputs
		EL016	room, ultrasound, vascular	NF		44	29	Refined equipment time to conform to established policies for technical equipment
94667	Chest wall manipula tion	EF023	table, exam	NF		1	35	Refined equipment time to conform to changes in clinical labor time
94668	Chest wall manipula tion	EF023	table, exam	NF		1	33	Refined equipment time to conform to changes in clinical labor time
94669	Mechani cal chest wall oscill	EF023	table, exam	NF		1	45	Refined equipment time to conform to changes in clinical labor time

HCPCS Code	HCPCS Code Descrip- tion	Input Code	Input Code Description	Non- Fac/ Fac	Labor Activity (if applicable)	RUC Recommen dation or Current Value (min or qty)	CMS Refine ment (min or qty)	Comment
95816	Eeg awake and drowsy	EQ330	EEG, digital, testing system (computer hardware, software & camera)	NF		116	107	Refined equipment time to conform to established policies for technical equipment
95819	Eeg awake and asleep	EQ330	EEG, digital, testing system (computer hardware, software & camera)	NF		148	139	Refined equipment time to conform to established policies for technical equipment
95822	Eeg coma or sleep only	EQ330	EEG, digital, testing system (computer hardware, software & camera)	NF		123	114	Refined equipment time to conform to established policies for technical equipment
99170	Anogenit al exam child w imag	ED005	camera, digital system, 12 megapixel (medical grade)	NF		50	60	Refined equipment time to conform to established policies for technical equipment
		ED021	computer, desktop, w- monitor	NF		50	0	Indirect practice expense
		EF015	mayo stand	NF		50	60	Refined equipment time to conform to established policies for technical equipment

HCPCS Code	HCPCS Code Descrip- tion	Input Code	Input Code Description	Non- Fac/ Fac	Labor Activity (if applicable)	RUC Recommen dation or Current Value (min or qty)	CMS Refine ment (min or qty)	Comment
		EF031	table, power	NF		50	60	Refined equipment time to conform to established policies for technical equipment
		EQ170	light, fiberoptic headlight w- source	NF		50	60	Refined equipment time to conform to established policies for technical equipment
		ES004	colposcope	NF		50	67	Refined equipment time to conform to established policies for technical equipment
		L051A	RN	NF	Coordinate pre-surgery services	0	3	CMS clinical review
		L051A	RN	NF	Other Clinical Activity (Preservice)	5	0	CMS clinical review
		L051A	RN	NF	Other Clinical Activity (Post Service)	15	3	CMS clinical review
		SA048	pack, minimum multi-specialty visit	F		1	0	Service period supplies are not included in the facility setting

HCPCS Code	HCPCS Code Descrip- tion	Input Code	Input Code Description	Non- Fac/ Fac	Labor Activity (if applicable)	RUC Recommen dation or Current Value (min or qty)	CMS Refine ment (min or qty)	Comment
		SB006	drape, non- sterile, sheet 40in x 60in	F		1	0	Service period supplies are not included in the facility setting
		SB022	gloves, non- sterile	F		1	0	Service period supplies are not included in the facility setting
		SD118	specula, vaginal	F		1	0	Service period supplies are not included in the facility setting
		SG008	applicator, cotton-tipped, non-sterile 6in	F		2	0	Service period supplies are not included in the facility setting
		SJ033	lubricating jelly (Surgilube)	F		1	0	Service period supplies are not included in the facility setting
		SL146	tubed culture media	F		2	0	Service period supplies are not included in the facility setting

HCPCS Code	HCPCS Code Descrip- tion	Input Code	Input Code Description	Non- Fac/ Fac	Labor Activity (if applicable)	RUC Recommen dation or Current Value (min or qty)	CMS Refine ment (min or qty)	Comment
		SL157	cup, sterile, 8 oz	F		1	0	Service period supplies are not included in the facility setting
		E	Specimen, solvent, and formalin disposal cost	NF		0.35	0	Indirect practice expense
G0461	Immuno histoche mistry,	E	Laboratory Information System with maintenance contract	NF		2	0	Included in equipment cost per minute calculation
Goloi	initial antibody	Е	Copath System Software	NF		2	0	Indirect practice expense
		EP043	water bath, general purpose (lab)	NF		8	5	CMS clinical review
		ER041	microtome	NF		8	5	CMS clinical review
G0462	Immuno histoche mistry,	EP112	Benchmark ULTRA automated slide preparation system	NF		33	15	CMS clinical review
G0402	subseque nt antibody	SL489	UtraView Universal Alkaline Phosphatase Red Detection Kit	NF		0.2	2	CMS clinical review

c. Establishing CY 2014 Interim Final Malpractice RVUs

According to our malpractice methodology discussed in section II.C, we are assigning malpractice RVUs for CY 2014 new, revised and potentially misvalued codes by utilizing a crosswalk to a source code with a similar malpractice risk. We have reviewed the AMA RUC recommended

malpractice source code crosswalks for CY 2014 new, revised and potentially misvalued codes, and we are accepting all of them on an interim final basis for CY 2014.

For CY 2014, we created two HCPCS G-codes. HCPCS code G0461 (Immunohistochemistry or immunocytochemistry, per specimen; first stain with separately identifiable antibody(ies)) was created to replace CPT code 88342 (immunohistochemistry or immunocytochemistry, each separately identifiable antibody per block, cytologic preparation, or hematologic smear; first separately identifiable antibody per slide), which is Invalid effective January 1, 2014. We believe CPT code 88342 has a similar malpractice risk-of-service as HCPCS code G0461. Therefore, we are assigning an interim final malpractice crosswalk of CPT code 88342 to HCPCS code G0461 on an interim final basis for CY 2014. HCPCS code G0462 (Immunohistochemistry or immunocytochemistry, per specimen; each additional stain with separately identifiable antibody(ies) (List separately in addition to code for primary procedure) was created to replace CPT code 88343 (immunohistochemistry or immunocytochemistry, each separately identifiable antibody per block, cytologic preparation, or hematologic smear; each additional separately identifiable antibody per slide (list separately in addition to code for primary procedure), which is invalid effective January 1, 2014. We believe CPT code 88343 has a similar malpractice risk-of-service as HCPCS code G0462. Therefore, we are assigning an interim final malpractice crosswalk of CPT code 88343 to HCPCS code G0462 on an interim final basis for CY 2014.

Table 30 lists the adjusted CY 2013 and new/revised CY 2014 HCPCS codes and their respective source codes used to set the interim final CY 2014 malpractice RVUs. The malpractice RVUs for these services are reflected in Addendum B of this CY 2014 PFS final rule with comment period.

Consistent with past practice when the MEI has been rebased or revised we proposed to make adjustments to ensure that estimates of the aggregate CY 2014 PFS payments for work, PE and malpractice are in proportion to the weights for these categories in the revised MEI. As discussed in the II.B. and II.D., the MEI is being revised, the PE and malpractice RVUs, and the CF are being adjusted accordingly. For more information on this, see those sections. We received no comments specifically on the adjustment to malpractice RVUs.

TABLE 30: Crosswalk for Establishing CY 2014 New/Revised/Potentially Misvalued Codes Malpractice RVUs

CY 2014 Ne	ew, Revised, or Potentially Misvalued HCPCS Code	S Malpractice Risk Factor Crosswalk HCPC Code			
10030	Guide cathet fluid drainage	37200	transcatheter biopsy		
13152	Cmplx rpr e/n/e/l 2.6-7.5 cm	13152	cmplx rpr e/n/e/l 2.6-7.5 cm		
17000	Destruct premalg lesion	17000	destruct premalg lesion		
17003	Destruct premalg les 2-14	17003	destruct premalg les 2-14		
17004	Destroy premal lesions 15/>	17004	destroy premal lesions 15/>		
17311	Mohs 1 stage h/n/hf/g	17311	mohs 1 stage h/n/hf/g		
17312	Mohs addl stage	17312	mohs addl stage		
17313	Mohs 1 stage t/a/l	17313	mohs 1 stage t/a/l		
17314	Mohs addl stage t/a/l	17314	mohs addl stage t/a/l		
17315	Mohs surg addl block	17315	mohs surg addl block		
19081	Bx breast 1st Lesion strtctc	32553	ins mark thor for rt perq		
19082	Bx breast add Lesion strtctc	64480	inj foramen epidural add-on		
19083	Bx breast 1st Lesion US imag	32551	insertion of chest tube		
19084	Bx breast add Lesion US imag	64480	inj foramen epidural add-on		
19085	Bx breast 1st lesion mr imag	36565	insert tunneled cv cath		
19086	Bx breast add lesion mr imag	76812	ob us detailed addl fetus		
19281	Perq device breast 1st imag	50387	change ext/int ureter stent		
19282	Perq device breast ea imag	76812	ob us detailed addl fetus		
19283	Perq dev breast 1st strtctc	50387	change ext/int ureter stent		
19284	Perq dev breast add strtctc	76812	ob us detailed addl fetus		
19285	Perq dev breast 1st us imag	36569	insert picc cath		
19286	Perq dev breast add us imag	76812	ob us detailed addl fetus		
19287	Perq dev breast 1st mr guide	32551	insertion of chest tube		
19288	Perq dev breast add mr guide	76812	ob us detailed addl fetus		
23333	Remove shoulder fb deep	23472	reconstruct shoulder joint		
23334	Shoulder prosthesis removal	23472	reconstruct shoulder joint		
23335	Shoulder prosthesis removal	23472	reconstruct shoulder joint		
24160	Remove elbow joint implant	24363	replace elbow joint		
24164	Remove radius head implant	23430	repair biceps tendon		
27130	Total hip arthroplasty	27130	total hip arthroplasty		
27236	Treat thigh fracture	27236	treat thigh fracture		
27446	Revision of knee joint	27446	revision of knee joint		
27447	Total knee arthroplasty	27447	total knee arthroplasty		
31237	Nasal/sinus endoscopy surg	31237	nasal/sinus endoscopy surg		

CY 2014 Ne	ew, Revised, or Potentially Misvalued HCPCS Code	Malprac	tice Risk Factor Crosswalk HCPCS Code
31238	Nasal/sinus endoscopy surg	31238	nasal/sinus endoscopy surg
31239	Nasal/sinus endoscopy surg	31239	nasal/sinus endoscopy surg
31240	Nasal/sinus endoscopy surg	31240	nasal/sinus endoscopy surg
33282	Implant pat-active ht record	33282	implant pat-active ht record
33284	Remove pat-active ht record	33284	remove pat-active ht record
33366	Treath replace aortic valve	33979	insert intracorporeal device
35301	Rechanneling of artery	35301	rechanneling of artery
35475	Repair arterial blockage	35475	repair arterial blockage
35476	Repair venous blockage	35476	repair venous blockage
36245	Ins cath abd/l-ext art 1st	36245	ins cath abd/l-ext art 1st
37217	Stent placemt retro carotid	37660	revision of major vein
37236	Open/perq place stent 1st	36247	ins cath abd/l-ext art 3rd
37237	Open/perq place stent ea add	37223	iliac revasc w/stent add-on
37238	Open/perq place stent same	36247	ins cath abd/l-ext art 3rd
37239	Open/perq place stent ea add	37223	iliac revasc w/stent add-on
37241	Vasc embolize/occlude venous	37204	transcatheter occlusion
37242	Vasc embolize/occlude artery	37204	transcatheter occlusion
37243	Vasc embolize/occlude organ	37204	transcatheter occlusion
37244	Vasc embolize/occlude bleed	37204	transcatheter occlusion
38240	Transplt allo hct/donor	38240	transplt allo hct/donor
43191	Esophagoscopy rigid trnso dx	31575	diagnostic laryngoscopy
43192	Esophagoscp rig trnso inject	31575	diagnostic laryngoscopy
43193	Esophagoscp rig trnso biopsy	31575	diagnostic laryngoscopy
43194	Esophagoscp rig trnso rem fb	31575	diagnostic laryngoscopy
43195	Esophagoscopy rigid balloon	31575	diagnostic laryngoscopy
43196	Esophagoscp guide wire dilat	31638	bronchoscopy revise stent
43197	Esophagoscopy flex dx brush	31575	diagnostic laryngoscopy
43198	Esophagosc flex trnsn biopsy	31575	diagnostic laryngoscopy
43200	Esophagoscopy flexible brush	43200	esophagoscopy flexible brush
43201	Esoph scope w/submucous inj	43201	esoph scope w/submucous inj
43202	Esophagoscopy flex biopsy	43202	esophagoscopy flex biopsy
43204	Esoph scope w/sclerosis inj	43204	esoph scope w/sclerosis inj
43205	Esophagus endoscopy/ligation	43205	esophagus endoscopy/ligation
43206	Esoph optical endomicroscopy	43200	esophagoscopy flexible brush
43211	Esophagoscop mucosal resect	43201	esoph scope w/submucous inj
43212	Esophagoscop stent placement	43219	esophagus endoscopy

CY 2014 New, Revised, or Potentially Misvalued HCPCS Code		Malpractice Risk Factor Crosswalk HCPC Code		
43213	Esophagoscopy retro balloon	43456	dilate esophagus	
43214	Esophagosc dilate balloon 30	43458	dilate esophagus	
43215	Esophagoscopy flex remove fb	43215	esophagoscopy flex remove fb	
43216	Esophagoscopy lesion removal	43216	esophagoscopy lesion removal	
43217	Esophagoscopy snare les remv	43217	esophagoscopy snare les remv	
43220	Esophagoscopy balloon <30mm	43220	esophagoscopy balloon <30mm	
43226	Esoph endoscopy dilation	43226	esoph endoscopy dilation	
43227	Esophagoscopy control bleed	43227	esophagoscopy control bleed	
43229	Esophagoscopy lesion ablate	43228	esoph endoscopy ablation	
43231	Esophagoscop ultrasound exam	43231	esophagoscop ultrasound exam	
43232	Esophagoscopy w/us needle bx	43232	esophagoscopy w/us needle bx	
43233	Egd balloon dil esoph30 mm/>	43271	endo cholangiopancreatograph	
43235	Egd diagnostic brush wash	43235	egd diagnostic brush wash	
43236	Uppr gi scope w/submuc inj	43236	uppr gi scope w/submuc inj	
43237	Endoscopic us exam esoph	43237	endoscopic us exam esoph	
43238	Egd us fine needle bx/aspir	43238	egd us fine needle bx/aspir	
43239	Egd biopsy single/multiple	43239	egd biopsy single/multiple	
43240	Egd w/transmural drain cyst	43240	egd w/transmural drain cyst	
43241	Egd tube/cath insertion	43241	egd tube/cath insertion	
43242	Egd us fine needle bx/aspir	43242	egd us fine needle bx/aspir	
43243	Egd injection varices	43243	egd injection varices	
43244	Egd varices ligation	43244	egd varices ligation	
43245	Egd dilate stricture	43245	egd dilate stricture	
43246	Egd place gastrostomy tube	43246	egd place gastrostomy tube	
43247	Egd remove foreign body	43247	egd remove foreign body	
43248	Egd guide wire insertion	43248	egd guide wire insertion	
43249	Esoph egd dilation <30 mm	43249	esoph egd dilation <30 mm	
43250	Egd cautery tumor polyp	43250	egd cautery tumor polyp	
43251	Egd remove lesion snare	43251	egd remove lesion snare	
43252	Egd optical endomicroscopy			
43253			egd us fine needle bx/aspir	
43254	Egd endo mucosal resection	43251 egd remove lesion snare		
43255	Egd control bleeding any	43255	egd control bleeding any	
43257	Egd w/thrml txmnt gerd	43257	egd w/thrml txmnt gerd	
43259	Egd us exam duodenum/jejunum	43259	egd us exam duodenum/jejunum	
43260	Ercp w/specimen collection	43260	ercp w/specimen collection	

CY 2014 New, Revised, or Potentially Misvalued HCPCS Code		Malpractice Risk Factor Crosswalk HCPC Code	
43261	Endo cholangiopancreatograph	43261	endo cholangiopancreatograph
43262	Endo cholangiopancreatograph	43262	endo cholangiopancreatograph
43263	Ercp sphincter pressure meas	43263	ercp sphincter pressure meas
43264	Ercp remove duct calculi	43264	ercp remove duct calculi
43265	Ercp lithotripsy calculi	43265	ercp lithotripsy calculi
43266	Egd endoscopic stent place	43256	uppr gi endoscopy w/stent
43270	Egd lesion ablation	43258	operative upper gi endoscopy
43273	Endoscopic pancreatoscopy	43273	endoscopic pancreatoscopy
43274	Ercp duct stent placement	43268	endo cholangiopancreatograph
43275	Ercp remove forgn body duct	43269	endo cholangiopancreatograph
43276	Ercp stent exchange w/dilate	43269	endo cholangiopancreatograph
43277	Ercp ea duct/ampulla dilate	43271	endo cholangiopancreatograph
43278	Ercp lesion ablate w/dilate	43272	endo cholangiopancreatograph
43450	Dilate esophagus 1/mult pass	43450	dilate esophagus 1/mult pass
43453	Dilate esophagus	43453	dilate esophagus
49405	Image cath fluid colxn visc	37200	transcatheter biopsy
49406	Image cath fluid peri/retro	37200	transcatheter biopsy
49407	Image cath fluid trns/vgnl	37200	transcatheter biopsy
50360	Transplantation of kidney	50360	transplantation of kidney
52332	Cystoscopy and treatment	52332	cystoscopy and treatment
52353	Cystouretero w/lithotripsy	52353	cystouretero w/lithotripsy
52356	Cysto/uretero w/lithotripsy	52353	cystouretero w/lithotripsy
62310	Inject spine cerv/thoracic	62310	inject spine cerv/thoracic
62311	Inject spine lumbar/sacral	62311	inject spine lumbar/sacral
62318	Inject spine w/cath crv/thrc	62318	inject spine w/cath crv/thrc
62319	Inject spine w/cath lmb/scrl	62319	inject spine w/cath lmb/scrl
63047	Remove spine lamina 1 lmbr	63047	remove spine lamina 1 lmbr
63048	Remove spinal lamina add-on	63048	remove spinal lamina add-on
63650	Implant neuroelectrodes	63650	implant neuroelectrodes
64613	Destroy nerve neck muscle	64613	destroy nerve neck muscle
64614	Destroy nerve extrem musc	em musc 64614 destroy nerve extrem m	
64616	Chemodenerv musc neck dyston	64613 destroy nerve neck muscle	
64617	Chemodener muscle larynx emg	31513 injection into vocal cord	
64642	Chemodenery 1 extremity 1-4	64614	destroy nerve extrem musc
64643	Chemodenery 1 extrem 1-4 ea	64614	destroy nerve extrem musc
64644	Chemodenery 1 extrem 5/> mus	64614	destroy nerve extrem musc

CY 2014 New, Revised, or Potentially Misvalued HCPCS Code		Malpractice Risk Factor Crosswalk HCPC Code	
64645	Chemodenerv 1 extrem 5/> ea	64614	destroy nerve extrem musc
64646	Chemodenery trunk musc 1-5	64614	destroy nerve extrem musc
64647	Chemodenery trunk musc 6/>	64614	destroy nerve extrem musc
66180	Implant eye shunt	66180	implant eye shunt
66183	Insert ant drainage device	65850	incision of eye
66185	Revise eye shunt	66185	revise eye shunt
67255	Reinforce/graft eye wall	67255	reinforce/graft eye wall
67914	Repair eyelid defect	67914	repair eyelid defect
67915	Repair eyelid defect	67915	repair eyelid defect
67916	Repair eyelid defect	67916	repair eyelid defect
67917	Repair eyelid defect	67917	repair eyelid defect
67921	Repair eyelid defect	67921	repair eyelid defect
67922	Repair eyelid defect	67922	repair eyelid defect
67923	Repair eyelid defect	67923	repair eyelid defect
67924	Repair eyelid defect	67924	repair eyelid defect
69210	Remove impacted ear wax uni	69210	remove impacted ear wax uni
70450	Ct head/brain w/o dye	70450	ct head/brain w/o dye
70460	Ct head/brain w/dye	70460	ct head/brain w/dye
70551	Mri brain stem w/o dye	70551	mri brain stem w/o dye
70552	Mri brain stem w/dye	70552	mri brain stem w/dye
70553	Mri brain stem w/o & w/dye	70553	mri brain stem w/o & w/dye
72141	Mri neck spine w/o dye	72141	mri neck spine w/o dye
72142	Mri neck spine w/dye	72142	mri neck spine w/dye
72146	Mri chest spine w/o dye	72146	mri chest spine w/o dye
72147	Mri chest spine w/dye	72147	mri chest spine w/dye
72148	Mri lumbar spine w/o dye	72148	mri lumbar spine w/o dye
72149	Mri lumbar spine w/dye	72149	mri lumbar spine w/dye
72156	Mri neck spine w/o & w/dye	72156	mri neck spine w/o & w/dye
72157	Mri chest spine w/o & w/dye	72157	mri chest spine w/o & w/dye
72158	Mri lumbar spine w/o & w/dye	72158	mri lumbar spine w/o & w/dye
72191	Ct angiograph pelv w/o&w/dye	72191 ct angiograph pelv w/o&w/d	
74174	Ct angio abd&pelv w/o&w/dye	74174 ct angio abd&pelv w/o&w/dy	
74175	Ct angio abdom w/o & w/dye	74175 ct angio abdom w/o & w/dye	
77001	Fluoroguide for vein device	77001	fluoroguide for vein device
77002	Needle localization by xray	77002	needle localization by xray
77003	Fluoroguide for spine inject	77003	fluoroguide for spine inject

CY 2014 New, Revised, or Potentially Misvalued HCPCS Code		Malpractice Risk Factor Crosswalk HCP Code	
77280	Set radiation therapy field	77280	set radiation therapy field
77285	Set radiation therapy field	77285	set radiation therapy field
77290	Set radiation therapy field	77290	set radiation therapy field
77293	Respirator motion mgmt simul	77470	special radiation treatment
77295	3-d radiotherapy plan	77295	3-d radiotherapy plan
77301	Radiotherapy dose plan imrt	77301	radiotherapy dose plan imrt
77336	Radiation physics consult	77336	radiation physics consult
77338	Design mlc device for imrt	77338	design mlc device for imrt
77372	Srs linear based	77372	srs linear based
77373	Sbrt delivery	77373	sbrt delivery
77402	Radiation treatment delivery	77402	radiation treatment delivery
77403	Radiation treatment delivery	77403	radiation treatment delivery
77404	Radiation treatment delivery	77404	radiation treatment delivery
77406	Radiation treatment delivery	77406	radiation treatment delivery
77407	Radiation treatment delivery	77407	radiation treatment delivery
77408	Radiation treatment delivery	77408	radiation treatment delivery
77409	Radiation treatment delivery	77409	radiation treatment delivery
77411	Radiation treatment delivery	77411 radiation treatment	
77412	Radiation treatment delivery	77412	radiation treatment delivery
77413	Radiation treatment delivery	77413	radiation treatment delivery
77414	Radiation treatment delivery	77414	radiation treatment delivery
77416	Radiation treatment delivery	77416	radiation treatment delivery
77417	Radiology port film(s)	77417	radiology port film(s)
77600	Hyperthermia treatment	77600	hyperthermia treatment
77785	Hdr brachytx 1 channel	77785	hdr brachytx 1 channel
77786	Hdr brachytx 2-12 channel	77786	hdr brachytx 2-12 channel
77787	Hdr brachytx over 12 chan	77787	hdr brachytx over 12 chan
78072	Parathyrd planar w/spect&ct	78452	ht muscle image spect mult
88112	Cytopath cell enhance tech	88112	cytopath cell enhance tech
88365	Insitu hybridization (fish)	88365	insitu hybridization (fish)
88367	Insitu hybridization auto	88367 insitu hybridization auto	
88368	Insitu hybridization manual	88368 insitu hybridization manual	
90785	Psytx complex interactive	90836 psytx pt&/fam w/e&m 45 min	
90791	Psych diagnostic evaluation	90846	family psytx w/o patient
90792	Psych diag eval w/med srvcs	90846	family psytx w/o patient
90832	Psytx pt&/family 30 minutes	90846	family psytx w/o patient

CY 2014 New, Revised, or Potentially Misvalued HCPCS Code		Malpractice Risk Factor Crosswalk HCPC Code	
90833	Psytx pt&/fam w/e&m 30 min	90846	family psytx w/o patient
90834	Psytx pt&/family 45 minutes	90846	family psytx w/o patient
90836	Psytx pt&/fam w/e&m 45 min	90846	family psytx w/o patient
90837	Psytx pt&/family 60 minutes	90846	family psytx w/o patient
90838	Psytx pt&/fam w/e&m 60 min	90846	family psytx w/o patient
90839	Psytx crisis initial 60 min	90837	psytx pt&/family 60 minutes
90840	Psytx crisis ea addl 30 min	90833	psytx pt&/fam w/e&m 30 min
90845	Psychoanalysis	90845	psychoanalysis
90846	Family psytx w/o patient	90846	family psytx w/o patient
90847	Family psytx w/patient	90847	family psytx w/patient
90853	Group psychotherapy	90853	group psychotherapy
91065	Breath hydrogen/methane test	91065	breath hydrogen/methane test
92521	Evaluation of speech fluency	96105	assessment of aphasia
92522	Evaluate speech production	96105	assessment of aphasia
92523	Speech sound lang comprehen	96105	assessment of aphasia
92524	Behavral qualit analys voice	92520	laryngeal function studies
93000	Electrocardiogram complete	93000	electrocardiogram complete
93005	Electrocardiogram tracing	93005	electrocardiogram tracing
93010	Electrocardiogram report	93010	electrocardiogram report
93582	Perq transcath closure pda	93580	transcath closure of asd
93583	Perq transcath septal reduxn	93580	transcath closure of asd
93880	Extracranial bilat study	93880	extracranial bilat study
93882	Extracranial uni/ltd study	93882	extracranial uni/ltd study
94667	Chest wall manipulation	94667	chest wall manipulation
94668	Chest wall manipulation	94668	chest wall manipulation
94669	Mechanical chest wall oscill	94668	chest wall manipulation
95816	Eeg awake and drowsy	95816	eeg awake and drowsy
95819	Eeg awake and asleep	95819	eeg awake and asleep
95822	Eeg coma or sleep only	95822	eeg coma or sleep only
95886	Musc test done w/n test comp	95886 musc test done w/n test c	
95887	Musc tst done w/n tst nonext	95887	musc tst done w/n tst nonext
95928	C motor evoked uppr limbs	95928	c motor evoked uppr limbs
95929	C motor evoked lwr limbs	95929	c motor evoked lwr limbs
96365	Ther/proph/diag iv inf init	96365	ther/proph/diag iv inf init
96366	Ther/proph/diag iv inf addon	96366	ther/proph/diag iv inf addon
96367	Tx/proph/dg addl seq iv inf	96367	tx/proph/dg addl seq iv inf

CY 2014 New, Revised, or Potentially Misvalued HCPCS Code		Malpractice Risk Factor Crosswalk HCPC Code	
96368	Ther/diag concurrent inf	96368	ther/diag concurrent inf
96413	Chemo iv infusion 1 hr	96413	chemo iv infusion 1 hr
96415	Chemo iv infusion addl hr	96415	chemo iv infusion addl hr
96417	Chemo iv infus each addl seq	96417	chemo iv infus each addl seq
98940	Chiropract manj 1-2 regions	98940	chiropract manj 1-2 regions
98941	Chiropract manj 3-4 regions	98941	chiropract manj 3-4 regions
98942	Chiropractic manj 5 regions	98942	chiropractic manj 5 regions
98943	Chiropract manj xtrspinl 1/>	98943	chiropract manj xtrspinl 1/>
99170	Anogenital exam child w imag	99170	anogenital exam child w imag
70450 26	Ct head/brain w/o dye	70450 26	ct head/brain w/o dye
70450 TC	Ct head/brain w/o dye	70450 TC	ct head/brain w/o dye
70460 26	Ct head/brain w/dye	70460 26	ct head/brain w/dye
70460 TC	Ct head/brain w/dye	70460 TC	ct head/brain w/dye
70551 26	Mri brain stem w/o dye	70551 26	mri brain stem w/o dye
70551 TC	Mri brain stem w/o dye	70551 TC	mri brain stem w/o dye
70552 26	Mri brain stem w/dye	70552 26	mri brain stem w/dye
70552 TC	Mri brain stem w/dye	70552 TC	mri brain stem w/dye
70553 26	Mri brain stem w/o & w/dye	70553 26	mri brain stem w/o & w/dye
70553 TC	Mri brain stem w/o & w/dye	ain stem w/o & w/dye 70553 tc mri brain stem w/o	
72141 26	Mri neck spine w/o dye	72141 26	mri neck spine w/o dye
72141 TC	Mri neck spine w/o dye	72141 TC	mri neck spine w/o dye
72142 26	Mri neck spine w/dye	72142 26	mri neck spine w/dye
72142 TC	Mri neck spine w/dye	72142 TC	mri neck spine w/dye
72146 26	Mri chest spine w/o dye	72146 26	mri chest spine w/o dye
72146 TC	Mri chest spine w/o dye	72146 TC	mri chest spine w/o dye
72147 26	Mri chest spine w/dye	72147 26	mri chest spine w/dye
72147 TC	Mri chest spine w/dye	72147 TC	mri chest spine w/dye
72148 26	Mri lumbar spine w/o dye	72148 26	mri lumbar spine w/o dye
72148 TC	Mri lumbar spine w/o dye	72148 TC	mri lumbar spine w/o dye
72149 26	Mri lumbar spine w/dye 72149 26 mri lumbar spine w/dye		mri lumbar spine w/dye
72149 TC	Mri lumbar spine w/dye	72149 TC mri lumbar spine w/dye	
72156 26	Mri neck spine w/o & w/dye	72156 26 mri neck spine w/o & w/dye	
72156 TC	Mri neck spine w/o & w/dye	72156 TC mri neck spine w/o & w/dye	
72157 26	Mri chest spine w/o & w/dye	72157 26	mri chest spine w/o & w/dye
72157 TC	Mri chest spine w/o & w/dye	72157 TC	mri chest spine w/o & w/dye
72158 26	Mri lumbar spine w/o & w/dye	72158 26	mri lumbar spine w/o & w/dye

CY 2014 New, Revised, or Potentially Misvalued HCPCS Code		Malpractice Risk Factor Crosswalk HCPCS Code	
72158 TC	Mri lumbar spine w/o & w/dye	72158 TC	mri lumbar spine w/o & w/dye
72191 26	Ct angiograph pelv w/o&w/dye	72191 26	ct angiograph pelv w/o&w/dye
72191 TC	Ct angiograph pelv w/o&w/dye	72191 TC	ct angiograph pelv w/o&w/dye
74174 26	Ct angio abd&pelv w/o&w/dye	74174 26	ct angio abd&pelv w/o&w/dye
74174 TC	Ct angio abd&pelv w/o&w/dye	74174 TC	ct angio abd&pelv w/o&w/dye
74175 26	Ct angio abdom w/o & w/dye	74175 26	ct angio abdom w/o & w/dye
74175 TC	Ct angio abdom w/o & w/dye	74175 TC	ct angio abdom w/o & w/dye
77001 26	Fluoroguide for vein device	77001 26	fluoroguide for vein device
77001 TC	Fluoroguide for vein device	77001 TC	fluoroguide for vein device
77002 26	Needle localization by xray	77002 26	needle localization by xray
77002 TC	Needle localization by xray	77002 TC	needle localization by xray
77003 26	Fluoroguide for spine inject	77003 26	fluoroguide for spine inject
77003 TC	Fluoroguide for spine inject	77003 TC	fluoroguide for spine inject
77280 26	Set radiation therapy field	77280 26	set radiation therapy field
77280 TC	Set radiation therapy field	77280 TC	set radiation therapy field
77285 26	Set radiation therapy field	77285 26	set radiation therapy field
77285 TC	Set radiation therapy field	77285 TC	set radiation therapy field
77290 26	Set radiation therapy field	77290 26	set radiation therapy field
77290 TC	Set radiation therapy field	77290 TC	set radiation therapy field
77293 26	Respirator motion mgmt simul	77470 26	special radiation treatment
77293 TC	Respirator motion mgmt simul	77470 TC	special radiation treatment
77295 26	3-d radiotherapy plan	77295 26	3-d radiotherapy plan
77295 TC	3-d radiotherapy plan	77295 TC	3-d radiotherapy plan
77301 26	Radiotherapy dose plan imrt	77301 26	radiotherapy dose plan imrt
77301 TC	Radiotherapy dose plan imrt	77301 TC	radiotherapy dose plan imrt
77338 26	Design mlc device for imrt	77338 26	design mlc device for imrt
77338 TC	Design mlc device for imrt	77338 TC	design mlc device for imrt
77600 26	Hyperthermia treatment	77600 26	hyperthermia treatment
77600 TC	Hyperthermia treatment	77600 TC	hyperthermia treatment
77785 26	Hdr brachytx 1 channel	77785 26	hdr brachytx 1 channel
77785 TC	Hdr brachytx 1 channel	77785 TC	hdr brachytx 1 channel
77786 26	Hdr brachytx 2-12 channel	77786 26 hdr brachytx 2-12 channel	
77786 TC	Hdr brachytx 2-12 channel	77786 TC	hdr brachytx 2-12 channel
77787 26	Hdr brachytx over 12 chan	77787 26	hdr brachytx over 12 chan
77787 TC	Hdr brachytx over 12 chan	77787 TC	hdr brachytx over 12 chan
88112 26	Cytopath cell enhance tech	88112 26	cytopath cell enhance tech

CY 2014 New, Revised, or Potentially Misvalued HCPCS Code		Malpract	ice Risk Factor Crosswalk HCPCS Code
88112 TC	Cytopath cell enhance tech	88112 TC	cytopath cell enhance tech
88365 26	Insitu hybridization (fish)	88365 26	insitu hybridization (fish)
88365 TC	Insitu hybridization (fish)	88365 TC	insitu hybridization (fish)
88367 26	Insitu hybridization auto	88367 26	insitu hybridization auto
88367 TC	Insitu hybridization auto	88367 TC	insitu hybridization auto
88368 26	Insitu hybridization manual	88368 26	insitu hybridization manual
88368 TC	Insitu hybridization manual	88368 TC	insitu hybridization manual
91065 26	Breath hydrogen/methane test	91065 26	breath hydrogen/methane test
91065 TC	Breath hydrogen/methane test	91065 TC	breath hydrogen/methane test
93880 26	Extracranial bilat study	93880 26	extracranial bilat study
93880 TC	Extracranial bilat study	93880 TC	extracranial bilat study
93882 26	Extracranial uni/ltd study	93882 26 extracranial uni/ltd st	
93882 TC	Extracranial uni/ltd study	93882 TC	extracranial uni/ltd study
95816 26	Eeg awake and drowsy	95816 26	eeg awake and drowsy
95816 TC	Eeg awake and drowsy	95816 TC	eeg awake and drowsy
95819 26	Eeg awake and asleep	95819 26	eeg awake and asleep
95819 TC	Eeg awake and asleep	95819 TC	eeg awake and asleep
95822 26	Eeg coma or sleep only	95822 26	eeg coma or sleep only
95822 TC	Eeg coma or sleep only	95822 TC	eeg coma or sleep only
95928 26	C motor evoked uppr limbs	95928 26	c motor evoked uppr limbs
95928 TC	C motor evoked uppr limbs	95928 TC	c motor evoked uppr limbs
95929 26	C motor evoked lwr limbs	95929 26	c motor evoked lwr limbs
95929 TC	C motor evoked lwr limbs	95929 TC	c motor evoked lwr limbs
G0453	Cont intraop neuro monitor	95920	intraop nerve test add-on
G0455	Fecal microbiota prep instil	91065	breath hydrogen/methane test
G0461	Immunohistochemistry, init	88342	immunohisto antibody slide
G0462	Immunohistochemistry, addl	88342	immunohisto antibody slide

F. Geographic Practice Cost Indices (GPCIs)

1. Background

Section 1848(e)(1)(A) of the Act requires us to develop separate Geographic Practice Cost Indices (GPCIs) to measure resource cost differences among localities compared to the national average for each of the three fee schedule components (that is, work, PE, and MP). The 89 total PFS localities are discussed in section II.F.3. of this final rule with comment period. Although requiring that the PE and MP GPCIs reflect the full relative cost differences, section 1848(e)(1)(A)(iii) of the Act requires that the work GPCIs reflect only one-quarter of the relative cost differences compared to the national average. In addition, section 1848(e)(1)(G) of the Act sets a permanent 1.5 work GPCI floor for services furnished in Alaska beginning January 1, 2009, and section 1848(e)(1)(I) of the Act sets a permanent 1.0 PE GPCI floor for services furnished in frontier states (as defined in section 1848(e)(1)(I) of the Act) beginning January 1, 2011. Additionally, section 1848(e)(1)(E) of the Act provided for a 1.0 floor for the work GPCIs, which was set to expire at the end of 2012. Section 602 of the ATRA amended the statute to extend the 1.0 floor for the work GPCIs through CY 2013 (that is, for services furnished no later than December 31, 2013).

Section 1848(e)(1)(C) of the Act requires us to review and, if necessary, adjust the GPCIs at least every 3 years. Section 1848(e)(1)(C) of the Act requires that "if more than 1 year has elapsed since the date of the last previous GPCI adjustment, the adjustment to be applied in the first year of the next adjustment shall be 1/2 of the adjustment that otherwise would be made." Therefore, since the previous GPCI update was implemented in CY 2011 and CY 2012, we proposed to phase in 1/2 of the latest GPCI adjustment in CY 2014.

We completed a review of the GPCIs and proposed new GPCIs, as well as a revision to the cost share weights that correspond to all three GPCIs in the CY 2014 proposed rule. We also calculated a corresponding geographic adjustment factor (GAF) for each PFS locality. The GAFs are a weighted composite of each area's work, PE and MP GPCIs using the national GPCI cost share weights. Although the GAFs are not used in computing the fee schedule payment for a specific service, we provide them

because they are useful in comparing overall areas costs and payments. The actual effect on payment for any actual service will deviate from the GAF to the extent that the proportions of work, PE and MP RVUs for the service differ from those of the GAF.

As noted above, section 602 of the ATRA extended the 1.0 work GPCI floor only through December 31, 2013. Therefore, the proposed CY 2014 work GPCIs and summarized GAFs do not reflect the 1.0 work floor. However, as required by sections 1848(e)(1)(G) and 1848(e)(1)(I) of the Act, the 1.5 work GPCI floor for Alaska and the 1.0 PE GPCI floor for frontier states are permanent, and therefore, applicable in CY 2014

2. GPCI Update

As discussed in the CY 2014 PFS proposed rule (78 FR 43322), the proposed updated GPCI values were calculated by a contractor to CMS. There are three GPCIs (work, PE, and MP), and all GPCIs are calculated through comparison to a national average for each type. Additionally, each of the three GPCIs relies on its own data source(s) and methodology for calculating its value as described below. Additional information on the proposed CY 2014 GPCI update may be found in our contractor's draft report, "Draft Report on the CY 2014 Update of the Geographic Practice Cost Index for the Medicare Physician Fee Schedule," which is available on the CMS website. It is located under the supporting documents section of the CY 2014 PFS proposed rule located at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html. Note: Our contractor's final report and associated analysis will be posted on the CMS website after publication of this final rule with comment period (under the downloads section of the CY 2014 PFS final rule.

a. Work GPCIs

The physician work GPCIs are designed to reflect the relative costs of physician labor by Medicare PFS locality. As required by statute, the physician work GPCI reflects one quarter of the relative wage differences for each locality compared to the national average.

To calculate the physician work GPCIs, we use wage data for seven professional specialty occupation categories, adjusted to reflect one-quarter of the relative cost differences for each locality compared to the national average, as a proxy for physicians' wages. Physicians' wages are not included in the occupation categories used in calculating the work GPCI because Medicare payments are a key determinant of physicians' earnings. Including physician wage data in calculating the work GPCIs would potentially introduce some circularity to the adjustment since Medicare payments typically contribute to or influence physician wages. That is, including physicians' wages in the physician work GPCIs would, in effect, make the indices, to some extent, dependent upon Medicare payments.

The physician work GPCI updates in CYs 2001, 2003, 2005, and 2008 were based on professional earnings data from the 2000 Census. However, for the CY 2011 GPCI update (75 FR 73252), the 2000 data were outdated and wage and earnings data were not available from the more recent Census because the "long form" was discontinued. Therefore, we used the median hourly earnings from the 2006 through 2008 Bureau of Labor Statistics (BLS) Occupational Employment Statistics (OES) wage data as a replacement for the 2000 Census data. The BLS OES data meet several criteria that we consider to be important for selecting a data source for purposes of calculating the GPCIs. For example, the BLS OES wage and employment data are derived from a large sample size of approximately 200,000 establishments of varying sizes nationwide from every metropolitan area and can be easily accessible to the public at no cost. Additionally, the BLS OES is updated regularly, and includes a comprehensive set of occupations and industries (for example, 800 occupations in 450 industries).

Because of its reliability, public availability, level of detail, and national scope, we believe the BLS OES continues to be the most appropriate source of wage and employment data for use in calculating the work GPCIs (and as discussed in section II.F.2.b the employee wage component and purchased services component of the PE GPCI). Therefore, for the proposed CY 2014 GPCI update, we used updated BLS OES data (2009 through 2011) as a replacement for the 2006 through 2008 data to compute the work GPCIs.

b. Practice Expense GPCIs

The PE GPCIs are designed to measure the relative cost difference in the mix of goods and services comprising practice expenses (not including malpractice expenses) among the PFS localities as compared to the national average of these costs. Whereas the physician work GPCIs (and as discussed later in this section, the MP GPCIs) are comprised of a single index, the PE GPCIs are comprised of four component indices (employee wages; purchased services; office rent; and equipment, supplies and other miscellaneous expenses). The employee wage index component measures geographic variation in the cost of the kinds of skilled and unskilled labor that would be directly employed by a physician practice. Although the employee wage index adjusts for geographic variation in the cost of labor employed directly by physician practices, it does not account for geographic variation in the cost of services that typically would be purchased from other entities, such as law firms, accounting firms, information technology consultants, building service managers, or any other third-party vendor. The purchased services index component of the PE GPCI (which is a separate index from employee wages) measures geographic variation in the cost of contracted services that physician practices would typically buy. (For more information on the development of the purchased service index, we refer readers to the CY 2012 PFS final rule with comment period (76 FR 73084 through 73085).) The office rent index component of the PE GPCI measures relative geographic variation in the cost of typical physician office rents. For the medical equipment, supplies, and miscellaneous expenses component, we believe there is a national market for these items such that there is not significant geographic variation in costs. Therefore, the "equipment, supplies and other miscellaneous expense" cost index component of the PE GPCI is given a value of 1.000 for each PFS locality.

For the previous update to the GPCIs (implemented in CY 2011 and CY 2012) we used 2006 through 2008 BLS OES data to calculate the employee wage and purchased services indices for the PE GPCI. As we discussed in the proposed rule because of its reliability, public availability, level of detail, and national scope, we continue to believe the BLS OES is the most appropriate data source for collecting wage and employment data. Therefore, in calculating the proposed CY 2014 GPCI update, we used

updated BLS OES data (2009 through 2011) as a replacement for the 2006 through 2008 data for purposes of calculating the employee wage component and purchased service index of the PE GPCI.

Office Rent Index Discussion

Since the inception of the PFS, we have used residential rent data (primarily the two-bedroom residential apartment rent data produced by the Department of Housing and Urban Development (HUD) at the 50th percentile) as the proxy to measure the relative cost difference in physician office rents. As discussed in the CY 2012 PFS final rule with comment period (76 FR 73084), we had concerns with the continued use of the HUD rental data because the data were not updated frequently and the Census "long form," which was used to collect the necessary base year rents for the HUD Fair Market Rent (FMR) data, was discontinued in CY 2010 and would no longer be available for future updates. Therefore, we examined the suitability of using 3-year (2006-2008) U.S. Census Bureau American Community Survey (ACS) rental data as a proxy for physician office rents to replace the HUD data. We determined that the ACS is one of the largest nationally representative surveys of household rents in the United States conducted annually by the U.S. Census Bureau, sampling approximately 3 million addresses with a recent response rate above 97 percent, and that it reports rental information for residences at the county level. Given that the ACS rental data provided a sufficient degree of reliability, is updated annually, and was expected to be available for future updates, we used the 2006 through 2008 ACS 3-year residential rent data as a replacement for the HUD data to create the office rent index for the CY 2012 PFS final rule with comment (76 FR 73084). For all the same reasons that we used the ACS data for the last GPCI update, we proposed to use updated ACS residential rent data (2008 through 2010) to calculate the office rent component of the PE GPCI. We noted in the proposed rule that when responding to the ACS survey, individuals also report whether utilities are included in their rent. Thus, the cost of utilities cannot be separated from "gross rents" since some individuals monthly rent also covers the cost of utilities. As discussed in section II.F.2.d., we combined the cost weights for fixed capital and utilities when assigning a proposed weight to the office rent component of the PE GPCI.

For many years, we have received requests from stakeholders to use commercial rent data instead of residential rent data to measure the relative cost differences in physician office rent. Additionally, in a report entitled "Geographic Adjustment in Medicare Payment, Phase I: Improving Accuracy," prepared for CMS under contract and released on September 28, 2011, the Institute of Medicine recommended that "a new source of data should be developed to determine the variation in the price of commercial office rent per square foot." The Institute of Medicine report did not identify any new data source and did not suggest how a new source of data might be developed. Because we could not identify a reliable commercial rental data source that is available on a national basis and includes data for non-metropolitan areas, we continued to use residential rent data for the CY 2012 GPCI update.

For the CY 2014 GPCI update, we continued our efforts to identify a reliable source of commercial rent data that could be used in calculating the rent index. We could not identify a nationally representative commercial rent data source that is available in the public sector. However, we identified a proprietary commercial rent data source that has potential for use in calculating the office rent indices in future years. To that end, we are attempting to negotiate an agreement with the proprietor to use the data for purposes of calculating the office rent component of the PE GPCI.

One of the challenges of using a proprietary data source is our ability to make information available to the public. When using government data, we are able to release all data for public consideration. However, when using a proprietary data source, it is likely that restrictions will be imposed on its use and our ability to disclose data. In such a situation, those wishing to replicate our calculations based on detailed data would also need to purchase the underlying proprietary data. We also believe that, generally speaking, a proprietary "for profit" data source is more susceptible to periodic changes in the criteria used for data collection, including possible changes in the data collected, the frequency at which the data is updated, changes in ownership, and the potential for termination of the survey vehicle entirely as changes are made to address economic pressures or opportunities. As such, we cannot predict that a given proprietary data source will be available in the format needed to develop office rent indices in the future. Since we have not identified a nationally representative commercial rent data

source that is available in the public sector, we believe it would be necessary to use a proprietary data source for commercial office rent data. That is, in the absence of using a proprietary data source, it is unlikely that we would be able to use commercial rent data to calculate the office rent index component of the PE GPCI. In the proposed rule we requested comments on the use of a proprietary commercial rent data source as well as whether there is a source for these data that is not proprietary.

c. Malpractice Expense (MP) GPCIs

The MP GPCIs measure the relative cost differences among PFS localities for the purchase of professional liability insurance (PLI). The MP GPCIs are calculated based on insurer rate filings of premium data for \$1 million to \$3 million mature claims-made policies (policies for claims made rather than services furnished during the policy term). For the CY 2011 GPCI update (sixth update) we used 2006 and 2007 malpractice premium data (75 FR 73256). The proposed CY 2014 MP GPCI update was developed using 2011 and 2012 premium data.

Additionally, for the past several GPCI updates, we were not able to collect MP premium data from insurer rate filings for the Puerto Rico payment locality. For the CY 2014 (seventh) GPCI update, we worked directly with the Puerto Rico Insurance Commissioner and Institute of Statistics to obtain data on MP insurance premiums that were used to calculate an updated MP GPCI for Puerto Rico. We noted in the proposed rule that using updated MP premium data would result in a 17 percent increase in MP GPCI for the Puerto Rico payment locality under the proposed fully phased-in seventh GPCI update, which would be effective CY 2015.

d. GPCI Cost Share Weights

To determine the cost share weights for the proposed CY 2014 GPCIs, we used the weights we proposed to use for the CY 2014 value for the revised 2006-based MEI as discussed in section II.D. of this final rule with comment period. As discussed in detail in that section, the MEI was rebased and revised in the CY 2011 PFS final rule with comment period (75 FR 73262 through 73277) to reflect the weighted-average annual price change for various inputs needed to provide physicians' services. We have historically updated the GPCI cost share weights to make them consistent with the most recent

update to the MEI, and proposed to do so again for CY 2014. We would note that consistent with this approach, in the CY 2011 proposed rule, the last time the MEI was revised, we proposed to update the GPCI cost share weights to reflect these revisions to the MEI. However, in response to public comments we did not finalize the proposal in the CY 2011 PFS final rule with comment period (75 FR 73258 and 73260), so that we could explore public comments received suggesting the reallocation of labor related costs from the medical equipment, supplies and miscellaneous component to the employee compensation component and comments received on the cost share weight for the rent index of the PE GPCI as well as to continue our analysis of the cost share weights attributed to the PE GPCIs as required by section 1848(e)(1)(H)(iv) of the Act.

In the CY 2012 PFS final rule (76 FR 73085 through 73086) we addressed commenter concerns regarding the inclusion of the cost share weight assigned to utilities within the office rent component of the PE GPCI and to geographically adjust wage related industries contained within the medical equipment, supplies and miscellaneous component of the PE GPCI. As a result, to accurately capture the utility measurement present in the ACS two bedroom gross rent data, the cost share weight for utilities was combined with the fixed capital portion to form the office rent index. Additionally, we developed a purchased service index to geographically adjust the labor-related components of the "All Other Services" and "Other Professional Expenses" categories of the 2006-based MEI market basket. Upon completing our analysis of the GPCI cost share weights (as required by the Act) and addressing commenters' concerns regarding the office rent and labor related industries previously contained in the medical equipment, supplies and other miscellaneous components of the PE GCPI, we updated the GPCI cost share weights consistent with the weights established in the 2006-based MEI in the CY 2012 PFS final rule (76 FR 73086).

The proposed revised 2006-based MEI cost share weights reflect our actuaries' best estimate of the weights associated with each of the various inputs needed to provide physicians' services. Use of the current MEI cost share weights also provides consistency across the PFS in the use of this data. Given that we have addressed previous commenters' concerns about the allocation of labor related costs (as

discussed earlier in this section) and that we have completed our analysis of the GPCI cost share weights (as required by the Act) we proposed to adopt the weights we proposed to use for the revised 2006-based MEI as the GPCI cost share weights for CY 2014.

Specifically, we proposed to change the cost share weights for the work GPCI (as a percentage of the total) from 48.266 percent to 50.866 percent, and the cost share weight for the PE GPCI from 47.439 percent to 44.839 percent. In addition we proposed to change the employee compensation component of the PE GPCI from 19.153 to 16.553 percentage points. The proposed cost share weights for the office rent component (10.223 percent), purchased services component (8.095 percent), and the medical equipment, supplies, and other miscellaneous expenses component (9.968 percent) of the PE GPCI and the cost share weight for the MP GPCI (4.295 percent) remained unchanged. A discussion of the specific MEI cost centers and the respective weights used to calculate each GPCI component (and subcomponent) is provided below.

(1) Work GPCIs

We proposed to adopt the proposed revised weight of 50.866 for the physician compensation cost category as the proposed work GPCI cost share weight.

(2) Practice Expense GPCIs

For the cost share weight for the PE GPCIs, we used the revised 2006-based MEI proposed weight for the PE category of 49.134 percent minus the PLI category weight of 4.295 percent (because the relative costs differences in malpractice expenses are measured by its own GPCI). Therefore, the proposed cost share weight for the PE GPCIs is 44.839 percent.

(a) Employee Compensation

For the employee compensation portion of the PE GPCIs, we used the proposed non-physician employee compensation category weight of 16.553 percent reflected in the revised 2006-based MEI.

(b) Office Rent

We set the PE GPCI office rent portion at 10.223 percent, which includes the proposed revised 2006-based MEI cost weights for fixed capital (reflecting the expenses for rent, depreciation on medical

buildings and mortgage interest) and utilities. As discussed previously in this section, we proposed to use 2008-2010 ACS rental data as the proxy for physician office rent. As mentioned previously, these data represent a gross rent amount and include data on utility expenditures. Since it is not possible to separate the utilities component of rent for all ACS survey respondents, we combined these two components to calculate office rent values that were used to calculate the office rent index component of the proposed PE GPCI. For purposes of consistency, we combined those two cost categories when assigning a proposed weight to the office rent component.

(c) Purchased Services

As discussed in section II.A. of this final rule with comment period, to be consistent with the purchased services index, we proposed to combine the current MEI cost share weights for "All Other Services" and "Other Professional Expenses" into a component called "All Other Professional Services." The proposed weight for "All Other Professional Services" is 8.095. As noted in the CY 2012 PFS final rule with comment period (76 FR 73084), we only adjust for locality cost differences of the labor-related share of the purchased services index. We determined that only 5.011 percentage points of the total 8.095 proposed weight are labor-related and, thus, would be adjusted for locality cost differences (5.011 adjusted purchased service + 3.084 non-adjusted purchased services = 8.095 total cost share weight). Therefore, only 62 percent (5.011/8.095) of the purchased service index is adjusted for geographic cost differences while the remaining 38 percent (3.084/8.095) of the purchased service index is not adjusted for geographic variation.

(d) Equipment, Supplies, and Other Miscellaneous Expenses

To calculate the medical equipment, supplies, and other miscellaneous expenses component, we removed PLI (4.295 percentage points), non-physician employee compensation (16.553 percentage points), fixed capital/utilities (10.223 percentage points), and purchased services (8.095 percentage points) from the total proposed PE category weight (49.134 percent). Therefore, the proposed cost share weight for the medical equipment, supplies, and other miscellaneous expenses component is 9.968 percent (49.134 - (4.295+16.553 + 10.223 + 8.095) = 9.968). As explained above, because we

believe there is a national market for these items, costs that fall within this component of the PE GPCI are not adjusted for geographic variation.

(3) Malpractice GPCIs

We proposed to use the PLI weight of 4.295 percent for the MP GPCI cost share weight. The proposed GPCI cost share weights for CY 2014 are displayed in Table 31.

TABLE 31: Proposed Cost Share Weights for CY 2014 GPCI Update

Expense Category	Current Cost Share Weight	Proposed CY 2014 Cost Share Weight
Work	48.266%	50.866%
Practice Expense (less PLI)	47.439%	44.839%
- Employee Compensation	19.153%	16.553%
- Office Rent	10.223%	10.223%
- Purchased Services	8.095%	8.095%
- Equipment, Supplies, Other	9.968%	9.968%
Malpractice Insurance	4.295%	4.295%
Total	100.000%	100.000%

e. PE GPCI Floor for Frontier States

Section 10324(c) of the Affordable Care Act added a new subparagraph (I) under section 1848(e)(1) of the Act to establish a 1.0 PE GPCI floor for physicians' services furnished in frontier States effective January 1, 2011. In accordance with section 1848(e)(1)(I) of the Act, beginning in CY 2011, we applied a 1.0 PE GPCI floor for physicians' services furnished in states determined to be frontier states. In general, a frontier state is one in which at least 50 percent of the counties are "frontier counties," which are those that have a population per square mile of less than 6. For more information on the criteria used to define a frontier state, we refer readers to the FY 2011 Inpatient Prospective Payment System final rule (75 FR 50160 through 50161). There are no changes in the states identified as "frontier states" for CY 2014. The qualifying states are reflected in Table 32. In accordance with the Act, we will apply a 1.0 PE GPCI floor for these states in CY 2014.

TABLE 32: Frontier States under Section 1848(E)(1)(I) of the Act (As added by section 10324(c) of the Affordable Care Act)

			Percent Frontier Counties (relative
State	Total Counties	Frontier Counties	to counties in the State)
Montana	56	45	80%
Wyoming	23	17	74%
North Dakota	53	36	68%
Nevada	17	11	65%
South Dakota	66	34	52%

f. Proposed GPCI Update

As explained above, the periodic review and adjustment of GPCIs is mandated by section 1848(e)(1)(C) of the Act. At each update, the proposed GPCIs are published in the PFS proposed rule to provide an opportunity for public comment and further revisions in response to comments prior to implementation. The proposed CY 2014 updated GPCIs for the first and second year of the 2-year transition, along with the GAFs, were displayed in Addenda D and E to the CY 2014 proposed rule available on the CMS website under the supporting documents section of the CY 2014 PFS proposed rule web page at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.

3. Payment Locality Discussion

a. Background

The current PFS locality structure was developed and implemented in 1997. There are currently 89 total PFS localities; 34 localities are statewide areas (that is, only one locality for the entire state). There are 52 localities in the other 16 states, with 10 states having 2 localities, 2 states having 3 localities, 1 state having 4 localities, and 3 states having 5 or more localities. The District of Columbia, Maryland, and Virginia suburbs, Puerto Rico, and the Virgin Islands are additional localities that make up the remainder of the total of 89 localities. The development of the current locality structure is described in detail in the CY 1997 PFS proposed rule (61 FR 34615) and the subsequent final rule with comment period (61 FR 59494).

Prior to 1992, Medicare payments for physicians' services were made under the reasonable charge system. Payments were based on the charging patterns of physicians. This resulted in large differences in payment for physicians' services among types of services, geographic payment areas, and physician specialties. Recognizing this, the Congress replaced the reasonable charge system with the Medicare PFS in the Omnibus Budget Reconciliation Act (OBRA) of 1989, and the PFS went into effect January 1, 1992. Payments under the PFS are based on the relative resources involved with furnishing services, and are adjusted to account for geographic variations in resource costs as measured by the GPCIs.

Payment localities originally were established under the reasonable charge system by local Medicare carriers based on their knowledge of local physician charging patterns and economic conditions. These localities changed little between the inception of Medicare in 1967 and the beginning of the PFS in 1992. Shortly after the PFS took effect, CMS undertook a study in 1994 that culminated in a comprehensive locality revision that was implemented in 1997 (61 FR 59494).

The revised locality structure reduced the number of localities from 210 to the current 89, and the number of statewide localities increased from 22 to 34. The revised localities were based on locality resource cost differences as reflected by the GPCIs. For a full discussion of the methodology, see the CY 1997 PFS final rule with comment period (61 FR 59494). The current 89 fee schedule areas are defined alternatively by state boundaries (for example, Wisconsin), metropolitan areas (for example, Metropolitan St. Louis, MO), portions of a metropolitan area (for example, Manhattan), or rest-of-state areas that exclude metropolitan areas (for example, rest of Missouri). This locality configuration is used to calculate the GPCIs that are in turn used to calculate payments for physicians' services under the PFS.

As stated in the CY 2011 PFS final rule with comment period (75 FR 73261), we require that changes to the PFS locality structure be done in a budget neutral manner within a state. For many years, before making any locality changes, we have sought consensus from among the professionals whose payments would be affected. In recent years, we have also considered more comprehensive changes to locality configuration. In 2008, we issued a draft comprehensive report detailing four different locality

configuration options (<u>www.cms.gov/physicianfeesched/downloads/ReviewOfAltGPCIs.pdf</u>). The alternative locality configurations in the report are described below.

- Option 1: CMS Core-Based Statistical Area (CBSA) Payment Locality Configuration:

 CBSAs are a combination of Office of Management and Budget (OMB's) Metropolitan Statistical Areas

 (MSAs) and Micropolitan Statistical Areas. Under this option, MSAs would be considered as urban

 CBSAs. Micropolitan Statistical Areas (as defined by OMB) and rural areas would be considered as nonurban (rest of state) CBSAs. This approach would be consistent with the areas used in the Inpatient

 Prospective Payment System (IPPS) pre-reclassification wage index, which is the hospital wage index for
 a geographic area (CBSA or non-CBSA) calculated from submitted hospital cost report data before
 statutory adjustments reconfigure, or "reclassify" a hospital to an area other than its geographic location,
 to adjust payments for differences in local resource costs in other Medicare payment systems. Based on
 data used in the 2008 locality report, this option would increase the number of PFS localities from 89 to
 439.
- Option 2: Separate High-Cost Counties from Existing Localities (Separate Counties): Under this approach, higher cost counties are removed from their existing locality structure, and they would each be placed into their own locality. This option would increase the number of PFS localities from 89 to 214, using a 5 percent GAF differential to separate high-cost counties.
- Option 3: Separate MSAs from Statewide Localities (Separate MSAs): This option begins with statewide localities and creates separate localities for higher cost MSAs (rather than removing higher cost counties from their existing locality as described in Option 2). This option would increase the number of PFS localities from 89 to 130, using a 5 percent GAF differential to separate high-cost MSAs.
- Option 4: Group Counties Within a State Into Locality Tiers Based on Costs (Statewide Tiers):

 This option creates tiers of counties (within each state) that may or may not be contiguous but share

 similar practice costs. This option would increase the number of PFS localities from 89 to 140, using a 5

 percent GAF differential to group similar counties into statewide tiers.

For a detailed discussion of the public comments on the contractor's 2008 draft report detailing four different locality configurations, we refer readers to the CY 2010 PFS proposed rule (74 FR 33534) and subsequent final rule with comment period (74 FR 61757). There was no public consensus on the options, although a number of commenters expressed support for Option 3 (separate MSAs from statewide localities) because the commenters believed this alternative would improve payment accuracy and could mitigate potential reductions to rural areas compared to Option 1 (CMS CBSAs).

In response to some public comments regarding the third of the four locality options, we had our contractor conduct an analysis of the impacts that would result from the application of Option 3. Those results were displayed in the final locality report released in 2011. The final report, entitled "Review of Alternative GPCI Payment Locality Structures – Final Report," may be accessed directly from the CMS website at

www.cms.gov/PhysicianFeeSched/downloads/Alt GPCI Payment Locality Structures Review.pdf.

Moreover, at our request, the Institute of Medicine conducted a comprehensive empirical study of the Medicare GAFs established under sections 1848(e) (PFS GPCI) and 1886(d)(3)(E) (IPPS hospital wage index) of the Act. These adjustments are designed to ensure Medicare payments reflect differences in input costs across geographic areas. The first of the Institute of Medicine's two reports entitled, "Geographic Adjustment in Medicare Payment, Phase I: Improving Accuracy" recommended that the same labor market definition should be used for both the hospital wage index and the physician geographic adjustment factor. Further, the Institute of Medicine recommended that MSAs and statewide non-metropolitan statistical areas should serve as the basis for defining these labor markets.

Under the Institute of Medicine's recommendations, MSAs would be considered as urban CBSAs. Micropolitan Areas (as defined by the OMB) and rural areas would be considered as non-urban (rest of state) CBSAs. This approach would be consistent with the areas used in the IPPS pre-reclassification wage index to make geographic payment adjustments in other Medicare payment systems. For more information on the Institute of Medicine's recommendations on the PFS locality structure, see the CY 2013 PFS final rule with comment period (77 FR 68949). We also provided our technical

analyses of the Institute of Medicine Phase I recommendations in a report released on the PFS website at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.

Additionally, the Phase I report can be accessed on the Institute of Medicine's website at http://www.iom.edu/Reports/2011/Geographic-Adjustment-in-Medicare-Payment-Phase-I-Improving-Accuracy.aspx.

b. Institute of Medicine Phase II Report Discussion

The Institute of Medicine's second report, entitled "Geographic Adjustment in Medicare Payment - Phase II: Implications for Access, Quality, and Efficiency" was released July 17, 2012 and can be accessed on the Institute of Medicine's website at http://www.iom.edu/Reports/2011/Geographic-Adjustment-in-Medicare-Payment-Phase-I-Improving-Accuracy.aspx.

The Phase II report evaluated the effects of geographic adjustment factors (hospital wage index and GPCIs) on the distribution of the health care workforce, quality of care, population health, and the ability to provide efficient, high value care. The Institute of Medicine's Phase II report also included an analysis of the impacts of implementing its recommendations for accuracy in geographic adjustments which include a CBSA-based locality structure under the PFS. The Institute of Medicine analysis found that adopting a CBSA-based locality structure under the PFS creates large changes in county GAF values; for example, approximately half of all US counties would experience a payment reduction. The Institute of Medicine also found that GPCIs calculated under a CBSA-based locality structure would result in lower GAFs in rural areas (relative to the national average) because the GPCI values for rural areas would no longer include metropolitan practice costs within the current "rest-of-state" or "statewide" localities.

(1) Institute of Medicine Phase II Report Recommendations

The Institute of Medicine developed recommendations for improving access to and quality of medical care. The recommendations included in the Institute of Medicine's Phase II report are summarized as follows:

 Recommendation 1: The Medicare program should develop and apply policies that promote access to primary care services in geographic areas where Medicare beneficiaries experience persistent access problems.

- Recommendation 2: The Medicare program should pay for services that improve access to primary and specialty care for beneficiaries in medically underserved urban and rural areas, particularly telehealth technologies.
- Recommendation 3: To promote access to appropriate and efficient primary care services, the Medicare program should support policies that would allow all qualified practitioners to practice to the full extent of their educational preparation.
- Recommendation 4: The Medicare program should reexamine its policies that provide location-based adjustments for specific groups of hospitals, and modify or discontinue them based on their effectiveness in ensuring adequate access to appropriate care.
- Recommendation 5: Congress should fund an independent ongoing entity, such as the National Health Care Workforce Commission, to support data collection, research, evaluations, and strategy development, and make actionable recommendations about workforce distribution, supply, and scope of practice.
- Recommendation 6: Federal support should facilitate independent external evaluations of ongoing workforce programs intended to provide access to adequate health services for underserved populations and Medicare beneficiaries. These programs include the National Health Services Corps, Title VII and VIII programs under the Public Health Service Act, and related programs intended to achieve these goals.

(2) Institute of Medicine Phase II Report Conclusions

The Institute of Medicine committee concluded that geographic payment adjustments under the PFS are not a strong determinant of access problems and not an appropriate mechanism for improving the distribution of the healthcare workforce, quality of care, population health, and the ability to provide efficient, high value care. Specifically, the Institute of Medicine committee stated "that there are wide discrepancies in

access to and quality of care across geographic areas particularly for racial and ethnic minorities. However, the variations do not appear to be strongly related to differences in or potential changes to fee for service payment" (Page. 6). The committee also concluded "that Medicare beneficiaries in some geographic pockets face persistent access and quality problems, and many of these pockets are in medically underserved rural and inner-city areas. However, geographic adjustment of Medicare payment is not an appropriate approach for addressing problems in the supply and distribution of the health care workforce. The geographic variations in the distribution of physicians, nurses and physician assistants, and local shortages that create access problems for beneficiaries should be addressed through other means" (Page 7). Moreover, the committee concluded that "geographic [payment] adjustment is not an appropriate tool for achieving policy goals such as improving quality of expanding the pool of providers available to see Medicare beneficiaries" (Page 9).

(3) CMS Summary Response to Institute of Medicine Phase II Report

The Institute of Medicine's Phase II report recommendations are broad in scope, do not propose specific recommendations for making changes to the GPCIs or PFS locality structure, or are beyond the statutory authority of CMS.

We agree with the Institute of Medicine's assessment that many counties would experience a payment reduction and that large payment shifts would occur as a result of implementing a CBSA-based locality configuration under the PFS. Based on our contractor's analysis, there would be significant redistributive impacts if we were to implement a policy that would reconfigure the PFS localities based on the Institute of Medicine's CBSA-based locality recommendation. Many rural areas would see substantial decreases in their corresponding GAF and GPCI values as higher cost counties are removed from current "rest of state" payment areas. Conversely, many urban areas, especially those areas that are currently designated as "rest of state" but are located within higher cost MSAs, would experience increases in their applicable GPCIs and GAFs. That is, given that urban and rural areas would no longer be grouped together (for example, as in the current 34 statewide localities), many rural areas would see a reduction in payment under a CBSA-based locality configuration.

As noted earlier in this section, we are assessing a variety of approaches to changing the locality structure under the PFS and will continue to study options for revising the locality structure. However, to fully assess the implications of proposing a nationwide locality reconfiguration under the PFS, we must also assess and analyze the operational changes necessary to implement a revised locality structure. Given that all options under consideration (including the Institute of Medicine's CBSA-based approach) would expand the number of current localities and result in payment reductions to primarily rural areas, presumably any nationwide locality reconfiguration could potentially be transitioned over a number of years (to phase-in the impact of payment reductions gradually, from year-to-year, instead of all at once). As such, transitioning from the current locality structure to a nationwide reconfigured locality structure would present operational and administrative challenges that need to be identified and addressed. Therefore, we have begun to assess the broad operational changes that would be involved in implementing a nationwide locality reconfiguration under the PFS. Accordingly, we believe that it would be premature to make any statements about potential changes we would consider making to the PFS localities at this time. Any changes to PFS fee schedule areas would be made through future notice and comment rulemaking.

The following is a summary of the comments we received regarding our proposed CY 2014 GPCI update and summary response to the Institute of Medicine's Phase II report recommendations.

<u>Comment</u>: A few commenters including a national medical association and state medical society expressed support for using more current data in calculating the GPCIs. Another commenter stated that the BLS OES provides the best data for calculating the work GPCI and the employee wage component and purchased service component of the PE GPCI.

Response: For the reasons outlined in the proposed rule, we agree with the commenters.

Comment: One state medical association expressed support for our proposal to use BLS OES data for calculating the geographic variation in physician work. The commenter stated that the BLS OES includes a large sample of data on wages and should be very reliable. However, the commenter raised concerns about using multi-year averages of wages in years that large demographic and economic changes may have occurred. The commenter contends that because the BLS OES data are so robust,

using three-year averages is not necessary or appropriate. The commenter suggested that GPCI updates based on BLS OES data should be based on the most recent annual data available, rather than multi-year averages.

Response: We agree with the commenter that the BLS OES data are a reliable and robust source of wage and earnings data. The BLS OES wage and earnings data released in any given year are aggregated using 6 semi-annual panels of data collected over 3 years (2 panels per year). The BLS does not produce 1-year wage and earnings data. According to the Occupational Employment Statistics Frequently Asked Questions: "Significant reductions in sampling error can be achieved by taking advantage of a full 3 years of data, covering 1.2 million establishments and about 62 percent of the employment in the United States. This feature is particularly important in improving the reliability of estimates for detailed occupations in small geographical areas. Combining multiple years of data is also necessary to obtain full coverage of the largest establishments. In order to reduce respondent burden, the OES survey samples these establishments with virtual certainty only once every three years." We also note that the BLS recognizes that labor costs change over time. To make the data from all 6 semi-annual panels comparable, the OES program uses the Employment Cost Index (ECI) to translate the occupationlevel wages from previous years into a wage number for the most recent year. The Occupational Employment Statistics Frequently Asked Questions may be accessed from the Bureau of Labor Statistics website at: http://www.bls.gov/oes/oes ques.htm. As discussed above, the OES FAQs explain that the use of multi-year averages improves reliability of the data and reduces sampling error. We agree with this assessment, and therefore, we will continue to use the BLS OES wage and earnings data that reflect multi-year averaging.

<u>Comment</u>: A few commenters stated that the proposed GPCI update results in lowering payment amounts to rural areas, which threatens patient access to physician services, including treatments for complex conditions such as cancer and lupus. Another commenter expressed support for the elimination of all geographic adjustment factors under the PFS. The commenter believes that lower GPCIs discourage physicians and practitioners from practicing in rural and underserved areas.

Response: As discussed previously, section 1848(e)(1)(A) of the Act requires us to develop separate GPCIs to measure resource cost differences among localities compared to the national average for each of the three fee schedule components. We do not have the authority to eliminate geographic payment adjustments under the PFS. We note that the GPCI values for many rural PFS areas, including many single state localities (and rest of state localities), will increase as a result of the CY 2014 GPCI update. However, because the statutory 1.0 work GPCI floor expires at the end of CY 2013, beginning January 1, 2014, PFS payment amounts will be calculated based upon the actual work GPCI for the locality rather than using the 1.0 work GPCI floor (except in Alaska where the statutory 1.5 work GPCI floor will continue to apply). Accordingly, the summarized GAFs, provided as noted above for purposes of illustration and comparison, demonstrate decreases in the work GPCIs for these same PFS localities.

Comment: A few commenters requested an extension of the statutorily-mandated 1.0 work GPCI floor, which expires on December 31, 2013.

Response: As discussed above, the 1.0 work GPCI floor is established by statute and expires on December 31, 2013. We do not have authority to extend the 1.0 work GPCI floor beyond December 31, 2013.

Comment: A few commenters urged us to reassess the professional occupational categories used to determine the relative cost differences in physician earnings for purposes of calculating the work GPCI. The commenters believe that the current inputs do not adequately measure the relative cost differences in physician salary across PFS localities. The commenters also mentioned a recent report published by MedPAC on the work GPCI, which recommended changes to the proxy occupations used in calculating the work GPCI. The commenters stated that the MedPAC study found that the data sources we currently rely upon for determining the work GPCI bear no correlation to physician earnings and that rural primary care physicians have higher wages than their urban counterparts. One commenter suggested that we use actual physician salaries (instead of proxy occupations) to determine the relative differences in physician wages. Another commenter urged us to modify the work GPCI to include "reference occupations that will accurately reflect the higher input costs of rural physician earnings."

Response: We appreciate the comments regarding the professional occupations used to determine the relative cost differences in physician earnings for purposes of calculating the work GPCI. As noted previously in this section, physicians' wages are not included in the occupation categories used in calculating the work GPCI because Medicare payments are a key determinant of physicians' earnings. Including physician wage data in calculating the work GPCIs would potentially introduce some circularity to the adjustment since Medicare payments typically contribute to or influence physician wages. In other words, including physicians' wages in the physician work GPCIs would, in effect, make the indices, to some extent, dependent upon Medicare payments, which in turn are affected by the indices. Additionally, as noted in the proposed rule the MedPAC was required by section 3004 of the MCTRJCA to submit a report to the Congress by June 15, 2013, assessing whether any adjustment under section 1848 of the Act to distinguish the difference in work effort by geographic area is appropriate and, if so, what that level should be and where it should be applied. In the report, MedPAC was required to also assess the impact of the work geographic adjustment under the Act, including the extent to which the floor on such adjustment impacts access to care. We also noted in the proposed rule that we did not have sufficient time to review this report, which was issued on June 14, 2013, in order to take the report into consideration for the proposed rule. We will be assessing the findings and recommendations from the MedPAC report and, and we will consider whether to make recommendations or proposals for changes in future rulemaking.

<u>Comment</u>: Several commenters noted that they appreciated our efforts to obtain more recent malpractice premium data from Puerto Rico for purposes of calculating the MP GPCIs. The commenters stated that a MP GPCI update for the Puerto Rico payment locality is long overdue.

Response: We agree with the commenters. By obtaining more recent malpractice premium insurance data, we were able to calculate an updated MP GPCI for the Puerto Rico payment locality using recent market share and rate filings data, as we were able to do for most other PFS localities.

<u>Comment</u>: One commenter stated that we did not use the most recent ACS residential rent data available (2009 through 2011) when calculating the rent index and encouraged us to use the most recent ACS residential rent data if it does not decrease the PE GPCI for Puerto Rico.

Response: We appreciate the commenter's suggestion to use 2009 through 2011 ACS data for the CY 2014 GPCI update. We note that there was insufficient time between the release of the 2009 through 2011 ACS data and the CY 2014 PFS proposed rule to allow us to use these data for the calculation of the proposed office rent component of the PE GPCI.

<u>Comment</u>: Many commenters requested an increase to the PE GPCI values for the Puerto Rico payment locality. The commenters believe it is necessary to increase payments to Puerto Rico to prevent the continued exodus of physicians to the U.S. mainland, as well as to maintain the quality of care, reflect inflation, and modernize equipment and supplies in Puerto Rico. The commenters also argue that doctors in Puerto Rico are required to provide the same services for lower reimbursement than those practicing in the U.S. mainland).

One commenter acknowledged that the work, PE and malpractice GPCIs for the Puerto Rico locality were increased as a result of the CY 2014 GPCI update, but noted that, even with the increases, Puerto Rico continues to be the lowest paid PFS locality and that its "neighboring locality," the Virgin Islands, unjustifiably receives a MP GPCI and PE GPCI of 1.0. The commenter also requested specific increases to the proposed PE GPCI for the Puerto Rico locality, most notably the rent component and medical equipment and supplies component, and referenced a previous study entitled "Cost of Medical Services in Puerto Rico," which included physician survey information on the costs of operating a medical practice in Puerto Rico.

In addition, the same commenter stated that the methodology used to determine the equipment and supplies component of the PE GPCI is unfair to Puerto Rico. For example, the commenter noted that the medical equipment and supplies component of the PE GPCI is currently not adjusted for geographic cost differences; therefore all PFS localities receive an index of 1.0 for the equipment and supplies component. The commenter stated that medical equipment and supplies cost more in Puerto Rico because

of the higher cost of shipping, noting, for example, that air and maritime shipping is more expensive than ground shipping. Because Puerto Rico is dependent on air and maritime shipping, the commenter believes that our presumption that most medical equipment and supplies are sold through a national market does not adequately capture the higher cost of shipping medical equipment and medical supplies to the Puerto Rico locality. The commenter urged us to increase the PE GPCI calculated for the Puerto Rico locality, "so that it is equal to, or more closely approximates, the PE GPCI calculated for the state with the lowest PE GPCI (in this case, West Virginia)."

Response: As noted previously in this section, we are required by section 1848(e)(1)(A) of the Act to develop separate GPCIs to measure relative resource cost differences among localities compared to the national average for each of the three fee schedule components; work, PE and MP expense and to update the GPCIs at least every 3 years. In the CY 2014 PFS proposed rule, we proposed to update the GPCIs for each Medicare PFS locality using updated data. For the CY 2014 GPCI update, we calculated updated GPCIs for the Puerto Rico locality using the same data sources and methodology as used for other PFS localities. To calculate the work GPCI and the employee compensation and purchased service components of the PE GPCI, we used 2009 through 2011 BLS OES data. To calculate the office rent component of the PE GPCI we used updated ACS data (2008 through 2010) as replacement for 2006 through 2008. With respect to the comment suggesting we assign the PE GPCI calculated for West Virginia to the Puerto Rico payment locality, we note that we are required to calculate GPCIs based upon the geographic cost differences between a specific PFS payment locality and the national average. As noted above, we have sufficient cost data to calculate GPCI values specific to the Puerto Rico payment locality. It would not be appropriate to assign a PE GPCI calculated for the West Virginia payment locality (based on data specific to West Virginia) to the Puerto Rico payment locality. Additionally, with respect to the comment on the differential between the GPCI values assigned to the Virgin Islands payment locality (as compared to the calculated GPCI values for the Puerto Rico payment locality), we note that when a locality has sufficient locality-specific data, we use those data to calculate GPCI values according to the established methodology. Given that there are sufficient locality-specific data for Puerto

Rico, we calculated the GPCI values for the Puerto Rico payment locality based upon data from Puerto Rico.

As previously mentioned, we continue to believe that the BLS OES and ACS are reliable data sources for measuring the relative cost differences in wages and rents. In preparation for the CY 2014 GPCI update, we reviewed the study previously submitted by stakeholders entitled "Cost of Medical Services in Puerto Rico." The study aimed to analyze medical practice costs as well as physicians' perceptions of cost trends in Puerto Rico. Broadly, many of the study's findings are not directly relevant to the GPCIs because the study largely measured increases in the cost of practicing medicine in the Puerto Rico locality over time, but did not compare Puerto Rico cost trends to those across other PFS localities. We note that updates to the GPCIs are based upon changes in the relative costs of operating a medical practice among all PFS localities and not changes in the costs within a specific locality. Further, the survey methodology did not claim to be representative of all physicians furnishing services in the Puerto Rico payment locality. The physician responses do not appear to be weighted to represent the population of physicians across the Puerto Rico payment locality.

Moreover, the study claimed (as did many of the commenters) that shipping and transportation expenses increase the cost of medical equipment and supplies in Puerto Rico relative to the U.S. mainland. In developing the proposed CY 2014 GPCI update, we evaluated the premise that Puerto Rico physicians incur higher shipping costs when purchasing medical equipment and supplies that should be reflected in the GPCIs. At our request, our contractor attempted to locate data sources specific to geographic variation in shipping costs for medical equipment and supplies. However, there does not appear to be a comprehensive national data source available. In light of the comment that shipping costs are more expensive for the Puerto Rico payment locality (and rural areas, as discussed later in this section by other commenters) we are requesting specific information regarding potential data sources for shipping costs for medical equipment and supplies that are accessible to the public, available on a national basis for both urban and rural areas, and updated regularly

Comment: One commenter asserted that residential rents are an inaccurate proxy for commercial (office) rents in Puerto Rico because the residential rental market is less developed in Puerto Rico as compared to the commercial rental market. The commenter noted that Puerto Rico's residential rental market is largely skewed towards the very low (and extremely low) end of the income scale. For example, the commenter stated that 30 percent of renters in Puerto Rico are subsidized by a HUD program, compared to a national average of about 12 percent. The commenter also mentioned that the ACS residential rent data (which are used to calculate the office rent index) includes utilities. The commenter stated that the cost of one utility, electricity, in Puerto Rico, is more than double the national average. However, the commenter believes the high cost of electricity and other utilities that physicians in Puerto Rico incur is not adequately captured in the ACS residential rental data, because nearly one third of all the renters in Puerto Rico receive utility allowances and therefore are not responsible for their utility costs.

Response: The ACS is designed to capture the total actual costs of both rent and utilities (i.e. gross rent) regardless of whether either or both are subsidized and regardless of whether utility costs are included in rent or paid separately. According to the American Community Survey and Puerto Rico Community Survey (PRCS) 2010 Subject Definitions: "Gross rent is the contract rent plus the estimated average monthly cost of utilities (electricity, gas, and water and sewer) and fuels (oils, coal, kerosene, wood, etc.) if these are paid by the renter (or paid for the renter by someone else)." (Page 17.) The rent portion of gross rent is "the monthly rent agreed to or contracted for, regardless of any furnishings, utilities, fees, meals, or services that may be included." (Page 15.) Contract rent data were obtained from Housing Question 15a of the 2010 American Community Survey and Puerto Rico Community Survey. Utility costs included in the rent payment were also captured in this question while utility costs paid separately from contract

rent were obtained from a different set of questions in the survey. For instance, according to the American Community Survey and Puerto Rico Community Survey 2010 Subject Definitions: "The data on utility costs were obtained from Housing Questions 11a through 11d in the 2010 American Community Survey. The questions were asked of occupied housing units. The questions about electricity and gas asked for the monthly costs, and the questions about water/sewer and other fuels (oil, coal, wood, kerosene, etc.) asked for the yearly costs. Costs are recorded if paid by or billed to occupants, a welfare agency, relatives, or friends [emphasis added]. Costs that are paid by landlords, included in the rent payment, or included in condominium or cooperative fees are excluded" (Page 37). Therefore, it is correct to say the ACS estimates of residential rent and utility costs account for subsidized utilities. The American Community Survey and Puerto Rico Community Survey 2010 Subject Definitions publication may be accessed from the Bureau of Census website at

http://www.census.gov/acs/www/Downloads/data_documentation/SubjectDefinitions/2010_ACS SubjectDefinitions.pdf.

<u>Comment</u>: One commenter stated that "our region's office rental rates are, by GPCI measurement, supposedly only one-third of the highest (cost) regions" and that Medical Group Management Association (MGMA) survey data do not support these findings. The commenter requested that relative cost differences be accurately determined before making any adjustment to the PE GPCI.

Response: We do not believe the MGMA rental information on physician office rent is an adequate source for calculating the office rent index component of the PE GPCI for the following reasons. First, although MGMA invites about 11,000 medical practices to complete each of the two surveys it conducts (cost survey and compensation survey), the response rates for

these surveys are typically below 20 percent and responses primarily capture information for physician practices operating in metropolitan areas. Second, in addition to the low response rates, MGMA has uneven response rates across regions due to the fact that MGMA relies on a convenience sample rather than a random sample. For example, almost twice as many Colorado practices completed the surveys compared to those in California; the survey also includes more provider responses from Minnesota (ranked 21st in population) than any other state. Finally, there are few observations for many small states; in fact, ten states have fewer than 10 observations each.

For the reasons discussed above, we do not believe the MGMA survey is a viable data source for determining the relative cost differences in rents across PFS localities. As discussed previously in this section, given its national representation, reliability, high response rate and frequent updates we continue to believe that the ACS residential rent data is the most appropriate data source available at this time for purposes of calculating the rent index of the PE GPCI.

Comment: We received mixed comments regarding the potential use of a proprietary commercial rent data source for purposes of calculating the rent index of the PE GPCI. For instance, a few commenters stated that we should continue to explore the possibility of using a commercial rent data source (but did not comment specifically on the potential use of proprietary data). One medical association stated that it would be helpful if we could "elucidate how incorporating the commercial rent data would impact the practice expense GPCI and payment rates in each Medicare payment locality." In contrast, three other commenters did not support the use of a proprietary commercial rent data source and urged us to continue using publicly available data. One association suggested that we "should use the most accurate publicly available datasets to set the GPCI adjustments…because…it is important for the public to have

an opportunity to comment on proposed changes, and they need access to information to provide meaningful comments." Another commenter stated that there is not a more reliable source of data for calculating physician office rents (than the ACS residential rent data) and that the ACS data serve as a reasonable proxy for the relative differences in rents across PFS localities. The same commenter expressed concern about the cost to the public of purchasing proprietary data and suggested that a commercial rent data source might be used to validate relative cost differences calculated from the ACS data (but not replace the ACS data).

Response: We appreciate the comments received on the potential use of a proprietary commercial rent data source. In the event we make a specific proposal to incorporate a commercial rent data source (either proprietary or publicly available) for calculating the office rent index of the PE GPCI, we would provide locality level impacts of such proposal and the opportunity for public comment as afforded through the rulemaking process.

<u>Comment</u>: A few commenters supported the continuation of the 1.0 PE GPCI floor for frontier states.

Response: The 1.0 PE GPCI floor will continue to be applied for states identified as "frontier states" in accordance with 1848(e)(1)(I) of the Act.

Comment: Two commenters stated that many rural areas that do not fall within the statutory definition of a frontier state also face challenges associated with patient access to "physician-furnished services." The commenters stated that, even if the 1.0 work GPCI floor is extended, the updates to the PE GPCIs disadvantage rural providers, most notably in the provision of drugs and biologicals administered in a physician's office. The commenters assert that rural practices have "low purchasing power" (because of lower patient volumes) and higher shipping costs (in comparison to urban areas). The same commenters urged us to take into

account the "unique challenges faced by rural physicians in non-designated frontier states" and to fully recognize the significant costs of providing health care in rural communities when updating the GPCIs.

Response: We appreciate the comments received on the PE GPCI for rural areas. As discussed previously in this section, we are required to update the GPCIs at least every 3 years to reflect the relative cost differences of operating a medical practice in each locality compared to the national average costs. We do not have authority to apply the 1.0 PE GPCI floor to states that do not meet the statutory definition of a frontier state. As discussed above in response to another commenter, we are requesting specific information regarding potential data sources for shipping costs for medical equipment and supplies – especially sources that are publicly available, collect data nationally with sufficient coverage in both urban and rural areas, and are updated at regular intervals.

Comment: Several state medical associations strongly opposed the proposed revised 2006-based MEI that moved compensation for nonphysician practitioners from the practice expense category to the physician compensation category, and the implications of that proposed change for the GPCIs. Because of those concerns, the commenters strongly objected to our proposal to update the GPCI cost share weights to make them consistent with the most recent update to the MEI. Additionally, the commenters expressed concern that the proposed changes in cost share weights used in calculating updated GPCIs would alone cause significant changes in CY 2014 PFS payment amounts.

Response: As discussed in section II.B. revisions to the MEI are used to adjust the RVUs under the PFS so that the work RVUs and PE RVUs (in the aggregate) are in the same proportions as in the MEI. We also make the necessary adjustments to achieve budget neutrality

for the year under the PFS. A discussion of how our adoption of the proposed MEI cost weight revisions affects the adjustment of work RVUs and PE RVUs is provided in section II.B. of this final rule with comment period.

With regard to the GPCIs, as noted in section II.F.2.d., we historically have updated the GPCI cost share weights (and more generally, as noted above, the RVUs under the PFS) to make them consistent with the most recent update to the MEI because the MEI cost share weights reflect our actuaries' best estimate of the weights associated with each of the various inputs needed to provide physician services. Use of the revised MEI weights for purposes of the GPCIs does not represent a change to the data sources or methodology used to calculate the GPCIs. For purposes of calculating GPCI values, the revised MEI weights only result in changes to the relative weighting within the PE GPCI (because there are no subcomponent cost share weights for the work GPCI or malpractice GPCI). Since the MEI weight only changed for the employee compensation subcomponent (for instance, the MEI weights for office rent, purchased services and equipment and supplies remained unchanged), the revised MEI affected the relative weight of all PE subcomponents (as a percentage of total PE GPCI). In other words, using the revised MEI cost share weights results in a lower weight for the employee compensation component as a percentage of the total PE GPCI and higher weights for office rents, purchased services, and medical equipment and supplies as a percentage of the total PE GPCI. Use of the revised MEI cost share weights has no implications for calculating the work GPCI values or malpractice GPCI values. Thus, we believe the comments on our proposal to adopt the revised 2006-based MEI weights predominately reflect concerns about the impact of the revised weights in terms of RVU redistribution and conversion factor adjustment, which is discussed in section II.B.2.f., rather than on their use in the calculation of GPCI values. An analysis isolating the impact of the

changes in the subcomponent weighting of the PE GPCIs is available on the CMS website under the supporting documents section of the CY 2014 PFS final rule web page at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.

We note that the MEI cost share weights are also used to calculate a geographic adjustment factor (GAF) for each PFS locality, weighting each locality's GPCIs (work, PE, and MP) by the corresponding national MEI cost share weight. However, as mentioned previously, we calculate the GAFs for purposes of comparing the approximate aggregate geographic payment adjustments among localities. The GAF is not used to calculate the geographically adjusted payment amount for individual services. Rather, the geographically adjusted payment amount is calculated by applying the actual GPCI values (for work, PE and malpractice) for the particular PFS locality to adjust the RVUs (for work, PE and MP) for a specific service.

Comment: A few national medical associations requested that CMS respond to the Institute of Medicine's "Recommendation 3" as contained in its Phase II report. The commenters noted that the Institute of Medicine recommended that the Medicare program should support policies that would allow all qualified practitioners to practice to the full extent of their educational preparation. The commenters believe "that there are numerous barriers in Medicare regulations, procedures, and instructions that prevent nurse practitioners and other health care providers from performing the full range of services they are educated and clinically prepared to deliver." However, the commenter did not provide specific examples as part of their submitted comments on the CY 2014 PFS proposed rule. Moreover, the commenter urged us to develop proposals to revise Medicare regulations and policies to address the need for primary care, including women's health and pediatric services, in underserved areas.

Response: The Institute of Medicine's Phase II report summary analysis indicates: "there are many inconsistencies in state laws regarding scope of practice and many NPs are more likely to locate in rural areas in states with more progressive, less restrictive regulations."

Additionally, the Institute of Medicine recommended that "given the shortage of primary care providers in the United States and specifically in rural areas, the committee agrees that it would be reasonable to remove barriers in Medicare and state licensing language so all qualified practitioners are able to practice to the full extent of their educational preparation in providing needed services for Medicare beneficiaries" (Page 10). We did not include any proposals based on this Institute of Medicine recommendation in the CY 2014 PFS proposed rule. Therefore, we believe the comments relating to this recommendation are beyond the scope of the CY 2014 PFS proposed rule.

Comment: We received several comments on the PFS locality structure that were not within the scope of the CY 2014 proposed rule. For example, several commenters requested a locality change for a specific county. Another commenter requested that we consider the operational impact of a locality reconfiguration on the provider community, including non-physician practitioners, before making changes to the PFS locality structure. Two state medical associations emphasized the need to reform PFS localities, preferring an MSA-based approach. One national association was opposed to locality changes resulting in payment reductions to rural areas and a rural physician clinic recommended that we do not make any changes to the PFS locality structure because increasing the number of localities would lower payments to rural physicians.

<u>Response</u>: We appreciate the suggestions for making revisions to the PFS locality structure. As discussed above, we did not propose changes to the PFS locality structure.

Result of Evaluation of Comments

After consideration of the public comments received on the CY 2014 GPCI update, we are finalizing the CY 2014 GPCI update as proposed. Specifically, we are using updated BLS OES data (2009 through 2011) as a replacement for 2006 through 2008 data for purposes of calculating the work GPCI and the employee compensation component and purchased services component of the PE GPCI. We are also using updated ACS data (2008 through 2010) as a replacement for 2006 through 2008 data for calculating the office rent component of the PE GPCI, and updated malpractice premium data (2011 and 2012) as a replacement for 2006 through 2007 data to calculate the MP GPCI. We also note that we do not adjust the medical equipment, supplies and other miscellaneous expenses component of the PE GPCI because we continue to believe there is a national market for these items such that there is not a significant geographic variation in costs. However, in light of comments suggesting that there are geographic differences in shipping costs for medical equipment and supplies, we are requesting specific information regarding potential data sources for these shipping costs – especially sources that are publicly available, nationally representative with sufficient coverage in both urban and rural areas, and updated at regular intervals. Additionally, we are finalizing our proposal to update the GPCI cost share weights consistent with the revised 2006-based MEI cost share weights finalized in section II.D. of this final rule with comment period. As discussed above in response to comments, use of the revised GPCI cost share weights changed the weighting of the subcomponents within the PE GPCI (employee wages, office rent, purchased services, and medical equipment and supplies).

The CY 2014 updated GPCIs and summarized GAFs by Medicare PFS locality may be found in Addenda D and E to the CY 2014 final rule available on the CMS website under the

supporting documents section of the CY 2014 proposed rule web page at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.

Additional information on the CY 2014 GPCI update may be found in our contractor's report, "Report on the CY 2014 Update of the Geographic Practice Cost Index for the Medicare Physician Fee Schedule," which is available on the CMS website. It is located under the supporting documents section of the CY 2014 PFS final rule with comment period located at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.

G. Allowed Expenditures for Physicians' Services and the Sustainable Growth Rate

1. Medicare Sustainable Growth Rate (SGR)

The SGR is an annual growth rate that applies to physicians' services paid by Medicare. The use of the SGR is intended to control growth in aggregate Medicare expenditures for physicians' services. Payments for services are not withheld if the percentage increase in actual expenditures exceeds the SGR. Rather, the PFS update, as specified in section 1848(d)(4) of the Act, is adjusted based on a comparison of allowed expenditures (determined using the SGR) and actual expenditures. If actual expenditures exceed allowed expenditures, the update is reduced. If actual expenditures are less than allowed expenditures, the update is increased.

Section 1848(f)(2) of the Act specifies that the SGR for a year (beginning with CY 2001) is equal to the product of the following four factors:

- (1) The estimated change in fees for physicians' services;
- (2) The estimated change in the average number of Medicare fee-for-service beneficiaries;
 - (3) The estimated projected growth in real Gross Domestic Product per capita; and
 - (4) The estimated change in expenditures due to changes in statute or regulations.

In general, section 1848(f)(3) of the Act requires us to determine the SGRs for 3 different time periods], using the best data available as of September 1 of each year. Under section 1848(f)(3) of the Act, (beginning with the FY and CY 2000 SGRs) the SGR is estimated and subsequently revised twice based on later data. (The Act also provides for adjustments to be made to the SGRs for FY 1998 and FY 1999. See the February 28, 2003 **Federal Register** (68 FR 9567) for a discussion of these SGRs). Under section 1848(f)(3)(C)(ii) of the Act, there are no further revisions to the SGR once it has been estimated and subsequently revised in each

of the 2 years following the preliminary estimate. In this final rule with comment, we are making our preliminary estimate of the CY 2014 SGR, a revision to the CY 2013 SGR, and our final revision to the CY 2012 SGR.

a. Physicians' Services

Section 1848(f)(4)(A) of the Act defines the scope of physicians' services covered by the SGR. The statute indicates that "the term 'physicians' services' includes other items and services (such as clinical diagnostic laboratory tests and radiology services), specified by the Secretary, that are commonly performed or furnished by a physician or in a physician's office, but does not include services furnished to a Medicare+Choice plan enrollee."

We published a definition of physicians' services for use in the SGR in the November 1, 2001 **Federal Register** (66 FR 55316). We defined physicians' services to include many of the medical and other health services listed in section 1861(s) of the Act. Since that time, the statute has been amended to add new Medicare benefits. As the statute changed, we modified the definition of physicians' services for the SGR to include the additional benefits added to the statute that meet the criteria specified in section 1848(f)(4)(A).

As discussed in the CY 2010 PFS final rule with comment period (74 FR 61961), the statute provides the Secretary with clear discretion to decide whether physician-administered drugs should be included or excluded from the definition of "physicians' services." Exercising this discretion, we removed physician-administered drugs from the definition of physicians' services in section 1848(f)(4)(A) of the Act for purposes of computing the SGR and the levels of allowed expenditures and actual expenditures beginning with CY 2010, and for all subsequent years. Furthermore, in order to effectuate fully the Secretary's policy decision to remove drugs

from the definition of physicians' services, we removed physician-administered drugs from the calculation of allowed and actual expenditures for all prior years.

Thus, for purposes of determining allowed expenditures, actual expenditures for all years, and SGRs beginning with CY 2010 and for all subsequent years, we specified that physicians' services include the following medical and other health services if bills for the items and services are processed and paid by Medicare carriers (and those paid through intermediaries where specified) or the equivalent services processed by the Medicare Administrative Contractors:

- Physicians' services.
- Services and supplies furnished incident to physicians' services, except for the expenditures for "drugs and biologicals which are not usually self-administered by the patient."
 - Outpatient physical therapy services and outpatient occupational therapy services,
- Services of PAs, certified registered nurse anesthetists, certified nurse midwives, clinical psychologists, clinical social workers, nurse practitioners, and certified nurse specialists.
 - Screening tests for prostate cancer, colorectal cancer, and glaucoma.
 - Screening mammography, screening pap smears, and screening pelvic exams.
 - Diabetes outpatient self-management training (DSMT) services.
 - Medical Nutrition Therapy (MNT) services.
- Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests (including outpatient diagnostic laboratory tests paid through intermediaries).
 - X-ray, radium, and radioactive isotope therapy.
- Surgical dressings, splints, casts, and other devices used for the reduction of fractures and dislocations.
 - Bone mass measurements.
 - An initial preventive physical exam.

- Cardiovascular screening blood tests.
- Diabetes screening tests.
- Telehealth services.
- Physician work and resources to establish and document the need for a power mobility device.
 - Additional preventive services.
 - Pulmonary rehabilitation.
 - Cardiac rehabilitation.
 - Intensive cardiac rehabilitation.
 - Kidney disease education (KDE) services.
 - Personalized prevention plan services

b. Preliminary Estimate of the SGR for 2014

Our preliminary estimate of the CY 2014 SGR is -16.7 percent. We first estimated the CY 2014 SGR in March 2013, and we made the estimate available to the MedPAC and on our website. Table 33 shows the March 2013 estimate and our current estimates of the factors included in the 2014 SGR. The majority of the difference between the March estimate and our current estimate of the CY 2014 SGR is explained by changes in estimated enrollment after our March estimate was prepared. Estimates of 2014 real per capita GDP are also higher than were included in our March 2013 estimate of the SGR.

Statutory Factors	March Estimate	Current Estimate
Fees	0.5 percent (1.005)	0.6 percent (1.006)
Enrollment	4.5 percent (1.045)	2.2 percent (1.022)
Real Per Capita GDP	0.6 percent (1.006)	0.8 percent (1.008)
Law and Regulation	-19.7 percent (0.803)	-19.6 percent (0.804)
Total	-15.2 percent (0.848)	-16.7 percent (0.833)

TABLE 33: CY 2014 SGR Calculation

Note: Consistent with section 1848(f)(2) of the Act, the statutory factors are multiplied, not added, to produce the total (that is, $1.006 \times 1.022 \times 1.008 \times 0.804 = 0.833$). A more detailed explanation of each figure is provided in section II.G.1.e. of this final rule with comment period.

c. Revised Sustainable Growth Rate for CY 2013

Our current estimate of the CY 2013 SGR is 1.8 percent. Table 34 shows our preliminary estimate of the CY 2013 SGR, which was published in the CY 2013 PFS final rule with comment period, and our current estimate. The majority of the difference between the preliminary estimate and our current estimate of the CY 2013 SGR is explained by adjustments to reflect intervening legislative changes that have occurred since publication of the CY 2013 final rule with comment period.

TABLE 34: CY 2013 SGR Calculation

Statutory Factors	Estimate from CY 2013 Final Rule	Current Estimate
Fees	0.3 percent (1.003)	0.4 Percent (1.004)
Enrollment	3.6 percent (1.036)	1.0 Percent (1.01)
Real Per Capita GDP	0.7 percent (1.007)	0.9 Percent (1.009)
Law and Regulation	-23.3 percent (0.767)	-0.5 Percent (0.995)
Total	-19.7 percent (0.803)	1.8 Percent (1.018)

Note: Consistent with section 1848(f)(2) of the Act, the statutory factors are multiplied, not added, to produce the total (that is, $1.004 \times 1.01 \times 1.009 \times 0.995 = 1.018$). A more detailed explanation of each figure is provided in section II.G.1.e. of this final rule with comment period.

d. Final Sustainable Growth Rate for CY 2012

The SGR for CY 2012 is 5.1 percent. Table 35 shows our preliminary estimate of the CY 2012 SGR from the CY 2012 PFS final rule with comment period, our revised estimate from the CY 2013 PFS

final rule with comment period, and the final figures determined using the best available data as of September 1, 2013.

TABLE 35: CY 2012 SGR Calculation

	Estimate from	Estimate from	
	CY 2012	CY 2013	
Statutory Factors	Final Rule	Final Rule	Final
Fees	0.6 percent (1.006)	0.6 percent (1.006)	0.6 Percent (1.006)
Enrollment	3.5 percent (1.035)	1.6 percent (1.016)	0.9 Percent (1.009)
Real Per Capita GDP	0.6 percent (1.006)	0.7 percent (1.007)	0.9 Percent (1.009)
Law and Regulation	-20.7 percent (0.793)	0.0 percent (1.000)	2.6 Percent (1.026)
Total	-16.9 percent (0.831)	2.3 percent (1.023)	5.1 Percent (1.051)

Note: Consistent with section 1848(f)(2) of the Act, the statutory factors are multiplied, not added, to produce the total (that is, $1.006 \times 1.009 \times 1.009 \times 1.026 = 1.051$). A more detailed explanation of each figure is provided in section II.G.1.e. of this final rule with comment period.

e. Calculation of CYs 2014, 2013, and 2012 SGRs

(1) Detail on the CY 2014 SGR

All of the figures used to determine the CY 2014 SGR are estimates that will be revised based on subsequent data. Any differences between these estimates and the actual measurement of these figures will be included in future revisions of the SGR and allowed expenditures and incorporated into subsequent PFS updates.

(a) Factor 1– Changes in Fees for Physicians' Services (Before Applying Legislative Adjustments) for CY 2014

This factor is calculated as a weighted average of the CY 2014 changes in fees for the different types of services included in the definition of physicians' services for the SGR.

Medical and other health services paid using the PFS are estimated to account for approximately 87.7 percent of total allowed charges included in the SGR in CY 2014 and are updated using the percent change in the MEI. As discussed in section A of this final rule with comment period, the

percent change in the MEI for CY 2014 is 0.8 percent. Diagnostic laboratory tests are estimated to represent approximately 12.3 percent of Medicare allowed charges included in the SGR for CY 2014. Medicare payments for these tests are updated by the Consumer Price Index for Urban Areas (CPI-U), which is 1.8 percent for CY 2014. Section 1833(h)(2)(A)(iv) of the Act requires that the CPI-U update applied to clinical laboratory tests be reduced by a multi-factor productivity adjustment (MFP adjustment) and, for each of years 2011 through 2015, by 1.75 percentage points (percentage adjustment). The MFP adjustment will not apply in a year where the CPI-U is zero or a percentage decrease for a year. Further, the application of the MFP adjustment shall not result in an adjustment to the fee schedule of less than zero for a year. However, the application of the percentage adjustment may result in an adjustment to the fee schedule being less than zero for a year and may result in payment rates for a year being less than such payment rates for the preceding year. The applicable productivity adjustment for CY 2014 is -0.8 percent. Adjusting the CPI-U update by the productivity adjustment results in a 1.0 percent (1.8 percent (CPI-U) minus 0.8 percent (MFP adjustment)) update for CY 2014. Additionally, the percentage reduction of 1.75 percent is applied for CYs 2011 through 2015, as discussed previously. Therefore, for CY 2014, diagnostic laboratory tests will receive an update of -0.8 percent (rounded). Table 36 shows the weighted average of the MEI and laboratory price changes for CY 2014.

TABLE 36: Weighted-Average of the MEI and Laboratory Price Changes for CY 2014

	Weight	Update
Physician	0.877	0.8%
Laboratory	0.123	-0.8%
Weighted-average	1.000	0.6%

We estimate that the weighted average increase in fees for physicians' services in CY 2014 under the SGR (before applying any legislative adjustments) will be 0.6 percent.

(b) Factor 2 – Percentage Change in the Average Number of Part B Enrollees from CY 2013 to CY 2014

This factor is our estimate of the percent change in the average number of fee-for-service enrollees from CY 2013 to CY 2014. Services provided to Medicare Advantage (MA) plan enrollees are outside the scope of the SGR and are excluded from this estimate. We estimate that the average number of Medicare Part B fee-for-service enrollees will increase by 2.2 percent from CY 2013 to CY 2014. Table 37 illustrates how this figure was determined.

TABLE 37: Average Number of Medicare Part B Fee-For-Service Enrollees from CY 2013 to CY 2014 (Excluding Beneficiaries Enrolled in MA Plans)

,	CY 2013	CY 2014
Overall	47.982 million	49.459 million
Medicare Advantage (MA)	14.837 million	15.569 million
Net	33.144 million	33.890 million
Percent Increase	1 percent	2.2 percent

An important factor affecting fee-for-service enrollment is beneficiary enrollment in MA plans. Because it is difficult to estimate the size of the MA enrollee population before the start of a CY, at this time we do not know how actual enrollment in MA plans will compare to current estimates. For this reason, the estimate may change substantially as actual Medicare fee-for-service enrollment for CY 2014 becomes known.

(c) Factor 3– Estimated Real Gross Domestic Product Per Capita Growth in CY 2014

We estimate that the growth in real GDP per capita from CY 2013 to CY 2014 will be 0.8 percent (based on the annual growth in the 10 year moving average of real GDP per capita 2005 through 2014). Our past experience indicates that there have also been changes in estimates of real GDP per capita growth made before the year begins and the actual change in real GDP per

capita growth computed after the year is complete. Thus, it is possible that this figure will change as actual information on economic performance becomes available to us in CY 2014.

(d) Factor 4 – Percentage Change in Expenditures for Physicians' Services Resulting From Changes in Statute or Regulations in CY 2014 Compared With CY 2013

The statutory and regulatory provisions that will affect expenditures in CY 2014 relative to CY 2013 are estimated to have an impact on expenditures of -19.6 percent. The impact is primarily due to the expiration of the physician fee schedule update specified in statute for CY 2013 only.

(2) Detail on the CY 2013 SGR

A more detailed discussion of our revised estimates of the four elements of the CY 2013 SGR follows.

(a) Factor 1 – Changes in Fees for Physicians' Services (Before Applying Legislative Adjustments) for CY 2013

This factor was calculated as a weighted-average of the CY 2013 changes in fees that apply for the different types of services included in the definition of physicians' services for the SGR in CY 2013.

We estimate that services paid using the PFS account for approximately 90.1 percent of total allowed charges included in the SGR in CY 2013. These services were updated using the CY 2013 percent change in the MEI of 0.8 percent. We estimate that diagnostic laboratory tests represent approximately 9.9 percent of total allowed charges included in the SGR in CY 2013. For CY 2013, diagnostic laboratory tests received an update of -3.0 percent.

Table 38 shows the weighted-average of the MEI and laboratory price changes for CY 2013.

TABLE 38:	Weighted-Average	e of the MEI, a	nd Laboratory l	Price Changes fo	or CY 2013

	Weight	Update
Physician	0.901	0.8
Laboratory	0.099	-3.0
Weighted-average	1.000	0.4

After considering the elements described in Table 38, we estimate that the weighted-average increase in fees for physicians' services in CY 2013 under the SGR was 0.4 percent. Our estimate of this factor in the CY 2013 PFS final rule with comment period was 0.3 percent (77 FR 69133).

(b) Factor 2 – Percentage Change in the Average Number of Part B Enrollees from CY 2012 to CY 2013

We estimate that the average number of Medicare Part B fee-for-service enrollees (excluding beneficiaries enrolled in Medicare Advantage plans) increased by 1.0 percent in CY 2013. Table 39 illustrates how we determined this figure.

TABLE 39: Average Number of Medicare Part B Fee-For-Service Enrollees from CY 2012 to CY 2013 (Excluding Beneficiaries Enrolled in MA Plans)

	CY 2012	CY 2013
Overall	46.405 million	47.982 million
Medicare Advantage (MA)	13.586 million	14.837 million
Net	32.818 million	33.144 million
Percent Increase	0.9 percent	1.0 percent

Our estimate of the 1.0 percent change in the number of fee-for-service enrollees, net of Medicare Advantage enrollment for CY 2013 compared to CY 2012, is different than our original estimate of an increase of 3.6 percent in the CY 2013 PFS final rule with comment period (77 FR 69133). While our current projection based on data from 8 months of CY 2013 differs from our original estimate of 0.4 percent when we had no actual data, it is still possible

that our final estimate of this figure will be different once we have complete information on CY 2013 fee-for-service enrollment.

(c) Factor 3 –Estimated Real GDP Per Capita Growth in CY 2013

We estimate that the growth in real GDP per capita will be 0.9 percent for CY 2013 (based on the annual growth in the 10-year moving average of real GDP per capita (2004 through 2013)). Our past experience indicates that there have also been differences between our estimates of real per capita GDP growth made prior to the year's end and the actual change in this factor. Thus, it is possible that this figure will change further as complete actual information on CY 2013 economic performance becomes available to us in CY 2014.

(d) Factor 4 – Percentage Change in Expenditures for Physicians' Services Resulting From Changes in Statute or Regulations in CY 2013 Compared With CY 2012

The statutory and regulatory provisions that affected expenditures in CY 2013 relative to CY 2012 are estimated to have an impact on expenditures of -0.5 percent. This impact is primarily due to the expiration of the PFS update specified in statute for CY 2013 only.

(3) Detail on the CY 2012 SGR

A more detailed discussion of our final revised estimates of the four elements of the CY 2012 SGR follows.

(a) Factor 1 – Changes in Fees for Physicians' Services for CY 2012

This factor was calculated as a weighted average of the CY 2012 changes in fees that apply for the different types of services included in the definition of physicians' services for the SGR in CY 2012.

We estimate that services paid under the PFS account for approximately 90 percent of total allowed charges included in the SGR in CY 2012. These services were updated using the

CY 2012 percent change in the MEI of 0.6 percent. We estimate that diagnostic laboratory tests represent approximately 10 percent of total allowed charges included in the SGR in CY 2012. For CY 2012, diagnostic laboratory tests received an update of 0.7 percent.

Table 40 shows the weighted-average of the MEI and laboratory price changes for CY 2012.

TABLE 40: Weighted-Average of the MEI, Laboratory, and Drug Price Changes for 2012

	Weight	Update
Physician	0.900	0.6
Laboratory	0.100	0.7
Weighted-average	1.00	0.6

After considering the elements described in Table 40, we estimate that the weighted-average increase in fees for physicians' services in CY 2012 under the SGR (before applying any legislative adjustments) was 0.6 percent. This figure is a final one based on complete data for CY 2012.

(b) Factor 2 – Percentage Change in the Average Number of Part B Enrollees from CY 2011 to CY 2012

We estimate the change in the number of fee-for-service enrollees (excluding beneficiaries enrolled in MA plans) from CY 2011 to CY 2012 was 0.9 percent. Our calculation of this factor is based on complete data from CY 2012. Table 41 illustrates the calculation of this factor.

TABLE 41: Average Number of Medicare Part B Fee-For-Service Enrollees from CY 2011 to CY 2012 (Excluding Beneficiaries Enrolled in MA Plans)

	CY 2011	CY 2012
Overall	44.906	46.405
Medicare Advantage (MA)	12.382	13.586
Net	32.524	32.818
Percent Change	•••••	0.9%

(c) Factor 3 – Estimated Real GDP Per Capita Growth in CY 2012

We estimate that the growth in real per capita GDP was 0.9 percent in CY 2012 (based on the annual growth in the 10-year moving average of real GDP per capita (2003 through 2012)). This figure is a final one based on complete data for CY 2012.

(d) Factor 4 – Percentage Change in Expenditures for Physicians' Services Resulting From Changes in Statute or Regulations in CY 2012 Compared With CY 2011.

Our final estimate for the net impact on expenditures from the statutory and regulatory provisions that affect expenditures in CY 2012 relative to CY 2011 is 2.6 percent. This is primarily an effect of the statutory requirements surrounding the temporary physician fee schedule update in CY 2012.

2. The Update Adjustment Factor (UAF)

Section 1848(d) of the Act provides that the PFS update is equal to the product of the MEI and the UAF. The UAF is applied to make actual and target expenditures (referred to in the statute as "allowed expenditures") equal. As discussed previously, allowed expenditures are equal to actual expenditures in a base period updated each year by the SGR. The SGR sets the annual rate of growth in allowed expenditures and is determined by a formula specified in section 1848(f) of the Act.

The calculation of the UAF is not affected by sequestration. Pursuant to 2 U.S.C. 906(d)(6), "The Secretary of Health and Human Services shall not take into account any reductions in payment amounts which have been or may be effected under [sequestration], for purposes of computing any adjustments to payment rates under such title XVIII". Therefore, allowed charges, which are unaffected by sequestration, were used to calculate physician expenditures in lieu of Medicare payments plus beneficiary cost-sharing. As a result, neither actual expenditures or allowed expenditures were adjusted to reflect the impact of sequestration.

a. Calculation under Current Law

Under section 1848(d)(4)(B) of the Act, the UAF for a year beginning with CY 2001 is equal to the sum of the following--

- Prior Year Adjustment Component. An amount determined by—
- ++ Computing the difference (which may be positive or negative) between the amount of the allowed expenditures for physicians' services for the prior year (the year prior to the year for which the update is being determined) and the amount of the actual expenditures for those services for that year;
- ++ Dividing that difference by the amount of the actual expenditures for those services for that year; and
 - ++ Multiplying that quotient by 0.75.
 - Cumulative Adjustment Component. An amount determined by—
- ++ Computing the difference (which may be positive or negative) between the amount of the allowed expenditures for physicians' services from April 1, 1996, through the end of the prior year and the amount of the actual expenditures for those services during that period;

++ Dividing that difference by actual expenditures for those services for the prior year as increased by the SGR for the year for which the UAF is to be determined; and

++ Multiplying that quotient by 0.33.

Section 1848(d)(4)(E) of the Act requires the Secretary to recalculate allowed expenditures consistent with section 1848(f)(3) of the Act. As discussed previously, section 1848(f)(3) specifies that the SGR (and, in turn, allowed expenditures) for the upcoming CY (CY 2014 in this case), the current CY (that is, CY 2013) and the preceding CY (that is, CY 2012) are to be determined on the basis of the best data available as of September 1 of the current year. Allowed expenditures for a year generally are estimated initially and subsequently revised twice. The second revision occurs after the CY has ended (that is, we are making the second revision to CY 2012 allowed expenditures in this final rule with comment).

Table 42 shows the historical SGRs corresponding to each period through CY 2014.

TABLE 42: Annual and Cumulative Allowed and Actual Expenditures for Physicians' Services from April 1, 1996 through the End of the Upcoming Calendar Year

Period	Annual Allowed Expenditures (\$ in billions)	Annual Actual Expenditures (\$ in billions)	Cumulative Allowed Expenditures (\$ in billions)	Cumulative Actual Expenditures (\$ in billions)	FY/CY SGR
4/1/96-3/31/97	47.0	47.0	47.0	47.0	
4/1/97-3/31/98	48.5	47.2	95.6	94.3	3.2
4/1/98-3/31/99	50.6	48.1	146.2	142.4	4.2
1/1/99-3/31/99	12.7	12.5	146.2	142.4	
4/1/99-12/31/99	40.5	37.2	186.7	179.6	6.9
1/1/99-12/31/99	53.2	49.7	186.7	179.6	
1/1/00-12/31/00	57.1	54.4	243.7	234.0	7.3
1/1/01-12/31/01	59.7	61.5	303.4	295.5	4.5
1/1/02-12/31/02	64.6	64.8	368.0	360.3	8.3
1/1/03-12/31/03	69.3	70.4	437.3	430.7	7.3
1/1/04-12/31/04	73.9	78.5	511.2	509.1	6.6
1/1/05-12/31/05	77.0	83.8	588.2	593.0	4.2
1/1/06-12/31/06	78.2	85.1	666.4	678.1	1.5
1/1/07-12/31/07	80.9	85.1	747.2	763.1	3.5
1/1/08-12/31/08	84.5	87.3	831.8	850.4	4.5
1/1/09-12/31/09	89.9	91.1	921.7	941.5	6.4

Period	Annual Allowed Expenditures (\$ in billions)	Annual Actual Expenditures (\$ in billions)	Cumulative Allowed Expenditures (\$ in billions)	Cumulative Actual Expenditures (\$ in billions)	FY/CY SGR
1/1/10-12/31/10	97.9	96	1,019.60	1,037.40	8.9
1/1/11-12/31/11	102.5	99.6	1,122.20	1,137.10	4.7
1/1/12-12/31/12	107.8	99.5	1,230.00	1,236.60	5.1
1/1/13-12/31/13	109.7	102.2	1,339.70	1,338.80	1.8
1/1/14-12/31/14	91.4	N/A	1,431.10	N/A	-16.7

⁽¹⁾ Allowed expenditures in the first year (April 1, 1996-March 31, 1997) are equal to actual expenditures. All subsequent figures are equal to quarterly allowed expenditure figures increased by the applicable SGR. Cumulative allowed expenditures are equal to the sum of annual allowed expenditures. We provide more detailed quarterly allowed and actual expenditure data on our website at the following address: http://www.cms.hhs.gov/SustainableGRatesConFact/. We expect to update the website with the most current information later this month.

Consistent with section 1848(d)(4)(E) of the Act, Table 42 includes our second revision of allowed expenditures for CY 2012, a recalculation of allowed expenditures for CY 2013, and our initial estimate of allowed expenditures for CY 2014. To determine the UAF for CY 2014, the statute requires that we use allowed and actual expenditures from April 1, 1996 through December 31, 2013 and the CY 2014 SGR. Consistent with section 1848(d)(4)(E) of the Act, we will be making revisions to the CY 2013 and CY 2014 SGRs and CY 2013 and CY 2014 allowed expenditures. Because we have incomplete actual expenditure data for CY 2013, we are using an estimate for this period. Any difference between current estimates and final figures will be taken into account in determining the UAF for future years.

We are using figures from Table 42 in the following statutory formula:

$$UAF_{14} = \frac{Target_{13} - Actual_{13}}{Actual_{13}} \times 0.75 + \frac{Target_{4/96 - 12/13} - Actual_{4/96 - 12/13}}{Actual_{13} \times SGR_{14}} \times 0.33$$

 $UAF_{14} = Update Adjustment Factor for CY 2014= 3.0 percent$

Target₁₃ = Allowed Expenditures for CY 2013= \$109.7 billion

 $Actual_{13}$ = Estimated Actual Expenditures for CY 2013 = \$102.2 billion

 ⁽²⁾ Allowed expenditures for the first quarter of 1999 are based on the FY 1999 SGR.
 (3) Allowed expenditures for the last three quarters of 1999 are based on the FY 2000 SGR.

Target_{4/96-12/13} = Allowed Expenditures from 4/1/1996 - 12/31/2013 = \$1,339.70 billion Actual_{4/96-12/13} = Estimated Actual Expenditures from 4/1/1996 - 12/31/2013 = \$1,338.80 billion SGR_{14} = -16.7 percent (0.833)

$$\frac{\$109.7 - \$102.2}{\$102.2} \times 0.75 + \frac{\$1339.70 - \$1338.80}{\$102.2 \times .833} \times 0.33 = 5.9\%$$

Section 1848(d)(4)(D) of the Act indicates that the UAF determined under section 1848(d)(4)(B) of the Act for a year may not be less than -0.07 or greater than 0.03. Since 0.059 (5.9 percent) is greater than 0.03, the UAF for CY 2014 will be 3 percent.

Section 1848(d)(4)(A)(ii) of the Act indicates that 1.0 should be added to the UAF determined under section 1848(d)(4)(B) of the Act. Thus, adding 1.0 to 0.03 makes the UAF equal to 1.03.

3. Percentage Change in the MEI for CY 2014

MEI is required by section 1842(b)(3) of the Act, which states that prevailing charge levels beginning after June 30, 1973 may not exceed the level from the previous year except to the extent that the Secretary finds, on the basis of appropriate economic index data, that the higher level is justified by year-to-year economic changes. The current form of the MEI was detailed in the CY 2010 PFS final rule (75 FR 73262), which updated the cost structure of the index from a base year of 2000 to 2006. Additional updates to the MEI are discussed in section II.D of this final rule with comment period.

The MEI measures the weighted-average annual price change for various inputs needed to produce physicians' services. The MEI is a fixed-weight input price index, with an adjustment for the change in economy-wide multifactor productivity. This index, which has CY 2006 base

year weights, is comprised of two broad categories: (1) physician's own time; and (2) physician's practice expense (PE).

The physician's compensation (own time) component represents the net income portion of business receipts and primarily reflects the input of the physician's own time into the production of physicians' services in physicians' offices. This category consists of two subcomponents: (1) wages and salaries; and (2) fringe benefits.

The physician's practice expense (PE) category represents nonphysician inputs used in the production of services in physicians' offices. This category consists of wages and salaries and fringe benefits for nonphysician staff (who cannot bill independently) and other nonlabor inputs. The physician's PE component also includes the following categories of nonlabor inputs: office expenses; medical materials and supplies; professional liability insurance; medical equipment; medical materials and supplies; and other professional expenses.

Table 43 lists the MEI cost categories with associated weights and percent changes for price proxies for the CY 2014 update. The CY 2014 final MEI update is 0.8 percent and reflects a 1.9 percent increase in physician's own time and a 1.4 percent increase in physician's PE. Within the physician's PE, the largest increase occurred in postage, which increased 4.9 percent.

For CY 2014, the increase in the MEI is 0.8 percent, which reflects an increase in the non-productivity adjusted MEI of 1.7 percent and a productivity adjustment of 0.9 percent (which is based on the 10-year moving average of economy-wide private nonfarm business multifactor productivity). The BLS is the agency that publishes the official measure of private non-farm business MFP. Please see http://www.bls.gov/mfp, which is the link to the BLS historical published data on the measure of MFP.

TABLE 43: Increase in the Medicare Economic Index Update for CY 2014¹

Revised Cost Category	2006 Revised Cost Weight ²	CY14 Update (percent)
MEI Total, productivity adjusted	100.000%	0.8
Productivity: 10-year moving average of MFP ¹	N/A ⁵	0.9
MEI Total, without productivity adjustment	100.000%	1.7
Physician Compensation ³	50.866%	1.9
Wages and Salaries	43.641%	1.9
Benefits	7.225%	2.2
Practice Expense	49.134%	1.4
Non-physician compensation	16.553%	1.7
Non-physician wages	11.885%	1.7
Non-health, non-physician wages	7.249%	1.8
Professional & Related	0.800%	1.9
Management	1.529%	1.8
Clerical	4.720%	1.8
Services	0.200%	1.5
Health related, non-physician wages	4.636%	1.4
Non-physician benefits	4.668%	1.9
Other Practice Expense	32.581%	1.2
Utilities	1.266%	0.7
Miscellaneous Office Expenses	2.478%	0.3
Chemicals	0.723%	-1.2
Paper	0.656%	1.1
Rubber & Plastics	0.598%	0.5
All other products	0.500%	1.9
Telephone	1.501%	0.0
Postage	0.898%	4.9
All Other Professional Services	8.095%	1.8
Professional, Scientific, and Tech. Services	2.592%	1.7
Administrative and support & waste	3.052%	1.9
All Other Services	2.451%	1.6
Capital	10.310%	0.7
Fixed	8.957%	0.7
Moveable	1.353%	0.7
Professional Liability Insurance ⁴	4.295%	1.5
Medical Equipment	1.978%	1.2
Medical supplies	1.760%	1.0

The forecasts are based upon the latest available Bureau of Labor Statistics data on the 10-year average of BLS private nonfarm business multifactor productivity published on June 28, 2013. (http://www.bls.gov/news.release/prod3.nr0.htm)

² The weights shown for the MEI components are the 2006 base-year weights, which may not sum to subtotals or totals because of rounding. The MEI is a fixed-weight, Laspeyres-type input price index whose category

weights indicate the distribution of expenditures among the inputs to physicians' services for CY 2006. To determine the MEI level for a given year, the price proxy level for each component is multiplied by its 2006 weight. The sum of these products (weights multiplied by the price index levels) overall cost categories yields the composite MEI level for a given year. The annual percent change in the MEI levels is an estimate of price change over time for a fixed market basket of inputs to physicians' services.

- ³ The measures of productivity, average hourly earnings, Employment Cost Indexes, as well as the various Producer and Consumer Price Indexes can be found on the Bureau of Labor Statistics Web site at http://stats.bls.gov.
- ⁴ Derived from a CMS survey of several major commercial insurers.
- ⁵ Productivity is factored into the MEI categories as an adjustment; therefore, no explicit weight exists for productivity in the MEI.

4. Physician and Anesthesia Fee Schedule Conversion Factors for CY 2014

The CY 2014 PFS CF is \$27.2006. The CY 2014 national average anesthesia CF is \$17.2283.

- a. Physician Fee Schedule Update and Conversion Factor
- (1) CY 2014 PFS Update

The formula for calculating the PFS update is set forth in section 1848(d)(4)(A) of the Act. In general, the PFS update is determined by multiplying the CF for the previous year by the percentage increase in the MEI less productivity times the UAF, which is calculated as specified under section 1848(d)(4)(B) of the Act.

(2) CY 2014 PFS Conversion Factor

Generally, the PFS CF for a year is calculated in accordance with section 1848(d)(1)(A) of the Act by multiplying the previous year's CF by the PFS update.

We note section 101 of the Medicare Improvements and Extension Act, Division B of the Tax Relief and Health Care Act of 2006 (MIEA-TRHCA) provided a 1-year increase in the CY 2007 CF and specified that the CF for CY 2008 must be computed as if the 1-year increase had never applied.

Section 101 of the Medicare, Medicaid, and SCHIP Extension Act of 2007 (MMSEA) provided a 6-month increase in the CY 2008 CF, from January 1, 2008, through June 30, 2008, and specified that the CF for the remaining portion of CY 2008 and the CFs for CY 2009 and subsequent years must be computed as if the 6-month increase had never applied.

Section 131 of the MIPPA extended the increase in the CY 2008 CF that applied during the first half of the year to the entire year, provided for a 1.1 percent increase to the CY 2009 CF, and specified that the CFs for CY 2010 and subsequent years must be computed as if the increases for CYs 2007, 2008, and 2009 had never applied.

Section 1011(a) of the DODAA and section 5 of the TEA specified a zero percent update for CY 2010, effective January 1, 2010 through March 31, 2010.

Section 4 of the Continuing Extension Act of 2010 (CEA) extended the zero percent update for CY 2010 through May 31, 2010.

Subsequently, section 101(a)(2) of the PACMBPRA provided for a 2.2 percent update to the CF, effective from June 1, 2010 to November 30, 2010.

Section 2 of the Physician Payment and Therapy Relief Act of 2010 (Pub. L. No. 111-286) extended the 2.2 percent through the end of CY 2010.

Section 101 of the MMEA provided a zero percent update for CY 2011, effective January 1, 2011 through December 31, 2011, and specified that the CFs for CY 2012 and subsequent years must be computed as if the increases in previous years had never applied.

Section 301 of the Temporary Payroll Tax Cut Continuation Act of 2011 (TPTCCA) provided a zero percent update effective January 1, 2012 through February 29, 2012, and specified that the CFs for subsequent time periods must be computed as if the increases in previous years had never applied.

Section 3003 of the Middle Class Tax Relief and Job Creation Act of 2012 (Job Creation Act) provided a zero percent update effective March 1, 2012 through December 31, 2012, and specified that the CFs for subsequent time periods must be computed as if the increases in previous years had never applied.

Section 601 of the American Taxpayer Relief Act (ATRA) of 2012 (Pub. L. 112-240) provided a zero percent update for CY 2013, effective January 1, 2013 through December 31, 2013, and specified that the CFs for subsequent time periods must be computed as if the increases in previous years had not been applied.

Therefore, under current law, the CF that would be in effect in CY 2013 had the prior increases specified above not applied is \$25.0070.

In addition, when calculating the PFS CF for a year, section 1848(c)(2)(B)(ii)(II) of the Act requires that increases or decreases in RVUs may not cause the amount of expenditures for the year to differ more than \$20 million from what it would have been in the absence of these changes. If this threshold is exceeded, we must make adjustments to preserve budget neutrality. We estimate that CY 2014 RVU changes would result in a decrease in Medicare physician expenditures of more than \$20 million. Accordingly, we are increasing the CF by 0.046 percent to offset this estimated decrease in Medicare physician expenditures due to the CY 2014 RVU changes. Furthermore, as discussed in section A of this final rule with comment period, we are increasing the CF by 4.72 percent in order to offset the decrease in Medicare physician payments due to the CY 2014 rescaling of the RVUs so that the proportions of total payments for the work, PE, and malpractice RVUs match the proportions in the final revised MEI for CY 2014.

Accordingly, we calculate the CY 2014 PFS CF to be \$27.2006. This final rule with comment period announces a reduction to payment rates for physicians' services in CY 2014 under the

SGR formula. These payment rates are currently scheduled to be reduced under the SGR system on January 1, 2014. The total reduction in the MPFS conversion factor between CY 2013 and CY 2014 under the SGR system will be 20.1 percent. By law, we are required to make these reductions in accordance with section 1848(d) and (f) of the Act, and these reductions can only be averted by an Act of Congress. While Congress has provided temporary relief from these reductions every year since 2003, a long-term solution is critical. We will continue to work with Congress to fix this untenable situation so doctors and beneficiaries no longer have to worry about the stability and adequacy of payments from Medicare under the Physician Fee Schedule.

We illustrate the calculation of the CY 2014 PFS CF in Table 44.

TABLE 44: Calculation of the CY 2014 PFS CF

Conversion Factor in effect in CY 2013		\$34.0230
CY 2013 Conversion Factor had statutory increases		\$25.0070
not applied		
CY 2014 Medicare Economic Index	0.8 percent (1.008)	
CY 2014 Update Adjustment Factor	3.0 percent (1.03)	
CY 2014 RVU Budget Neutrality Adjustment	0.046 percent (1.00046)	
CY 2014 Rescaling to Match MEI Weights Budget	4.718 percent (1.04718)	
Neutrality Adjustment		
CY 2014 Conversion Factor		\$27.2006
Percent Change from Conversion Factor in		-20.1%
effect in CY 2013 to CY 2014 Conversion Factor		

We note payment for services under the PFS will be calculated as follows:

Payment = [(Work RVU x Work GPCI) + (PE RVU x PE GPCI) + (Malpractice RVU x Malpractice GPCI)] x CF.

b. Anesthesia Conversion Factor

We calculate the anesthesia CF as indicated in Table 45. Anesthesia services do not have RVUs like other PFS services. Therefore, we account for any necessary RVU adjustments

through an adjustment to the anesthesia CF to simulate changes to RVUs. More specifically, if there is an adjustment to the work, PE, or malpractice RVUs, these adjustments are applied to the respective shares of the anesthesia CF as these shares are proxies for the work, PE, and malpractice RVUs for anesthesia services. Information regarding the anesthesia work, PE, and malpractice shares can be found at the following: https://www.cms.gov/center/anesth.asp.

The anesthesia CF in effect in CY 2013 is \$ 21.9243. As explained previously, in order to calculate the CY 2014 PFS CF, the statute requires us to calculate the CFs for all previous years as if the various legislative changes to the CFs for those years had not occurred. Accordingly, under current law, the anesthesia CF in effect in CY 2013 had statutory increases not applied is \$16.1236. The percent change from the anesthesia CF in effect in CY 2013 to the CF for CY 2014 is –21.4 percent. We illustrate the calculation of the CY 2014 anesthesia CF in Table 45.

TABLE 45: Calculation of the CY 2014 Anesthesia CF

2013 National Average Anesthesia Conversion Factor in		\$21.9243
effect in CY 2013		
2013 National Anesthesia Conversion Factor had		\$16.1236
Statutory Increases Not Applied		
CY 2014 Medicare Economic Index	0.8 (1.008)	
CY 2014 Update Adjustment Factor	3.0 (1.003)	
CY 2014 Budget Neutrality Work and Malpractice	0.046 (1.00046)	
Adjustment		
CY 2014 Rescaling to Match MEI Weights Budget	4.718 percent (1.4718)	
Neutrality Adjustment		
CY 2014 Anesthesia Fee Schedule Practice Expense	.9823 (.9823)	
Adjustment		
CY 2014 Anesthesia Conversion Factor		\$17.2283
Percent Change from 2013 to 2014		-21.4%

H. Medicare Telehealth Services for the Physician Fee Schedule

- 1. Billing and Payment for Telehealth Services
- a. History

Prior to January 1, 1999, Medicare coverage for services delivered via a telecommunications system was limited to services that did not require a face-to-face encounter under the traditional model of medical care. Examples of these services included interpretation of an x-ray, electroencephalogram tracing, and cardiac pacemaker analysis.

Section 4206 of the BBA provided for coverage of, and payment for, consultation services delivered via a telecommunications system to Medicare beneficiaries residing in rural health professional shortage areas (HPSAs) as defined by the Public Health Service Act. Additionally, the BBA required that a Medicare practitioner (telepresenter) be with the patient at the time of a teleconsultation. Further, the BBA specified that payment for a teleconsultation had to be shared between the consulting practitioner and the referring practitioner and could not exceed the fee schedule payment that would have been made to the consultant for the service furnished. The BBA prohibited payment for any telephone line charges or facility fees associated with the teleconsultation. We implemented this provision in the CY 1999 PFS final rule with comment period (63 FR 58814).

Effective October 1, 2001, section 223 of the Medicare, Medicaid and SCHIP Benefits

Improvement Protection Act of 2000 (BIPA) (Pub. L. 106-554) added section 1834(m) to the Act, which significantly expanded Medicare telehealth services. Section 1834(m)(4)(F)(i) of the Act defines

Medicare telehealth services to include consultations, office visits, office psychiatry services, and any additional service specified by the Secretary, when delivered via a telecommunications system. We first implemented this provision in the CY 2002 PFS final rule with comment period (66 FR 55246). Section 1834(m)(4)(F)(ii) of the Act required the Secretary to establish a process that provides for annual updates to the list of Medicare telehealth services. We established this process in the CY 2003 PFS final rule with comment period (67 FR 79988).

As specified in regulations at §410.78(b), we generally require that a telehealth service be furnished via an interactive telecommunications system. Under §410.78(a)(3), an interactive telecommunications system is defined as, "multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner. Telephones, facsimile machines, and electronic mail systems do not meet the definition of an interactive telecommunications system." An interactive telecommunications system is generally required as a condition of payment; however, section 1834(m)(1) of the Act allows the use of asynchronous "store-and-forward" technology when the originating site is a federal telemedicine demonstration program in Alaska or Hawaii. As specified in regulations at §410.78(a)(1), store-and-forward means the asynchronous transmission of medical information from an originating site to be reviewed at a later time by the practitioner at the distant site.

Medicare telehealth services may be furnished to an eligible telehealth individual notwithstanding the fact that the practitioner furnishing the telehealth service is not at the same location as the beneficiary. An eligible telehealth individual means an individual enrolled under Part B who receives a telehealth service furnished at an originating site. Under the BIPA, originating sites were limited under section 1834(m)(3)(C) of the Act to specified medical facilities located in specific geographic areas. The initial list of telehealth originating sites included the office of a practitioner, CAH, a rural health clinic (RHC), a federally qualified health center (FQHC) and a hospital (as defined in section 1861(e) of the Act). More recently, section 149 of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110-275) (MIPPA) expanded the list of telehealth originating sites to include a hospital-based renal dialysis center, a skilled nursing facility (SNF), and a community mental health center (CMHC). To serve as a telehealth originating site, the Act requires that a site must also be located in an area designated as a rural HPSA, in a county that is not in a MSA, or must be an entity that participates in a federal telemedicine demonstration project that has been approved by (or receives funding from) the Secretary as of December 31, 2000. Finally, section 1834(m) of the Act does not require the eligible telehealth individual to be with a telepresenter at the originating site.

b. Current Telehealth Billing and Payment Policies

As noted previously, Medicare telehealth services can only be furnished to an eligible telehealth beneficiary in a qualifying originating site. An originating site is defined as one of the specified sites where an eligible telehealth individual is located at the time the service is being furnished via a telecommunications system. The originating sites authorized by the statute are as follows:

- Offices of a physician or practitioner;
- Hospitals;
- CAHs;
- RHCs;
- FQHCs;
- Hospital-Based or Critical Access Hospital-Based Renal Dialysis Centers (including Satellites);
- SNFs;
- CMHCs.

Currently approved Medicare telehealth services include the following:

- Initial inpatient consultations;
- Follow-up inpatient consultations;
- Office or other outpatient visits;
- Individual psychotherapy;
- Pharmacologic management;
- Psychiatric diagnostic interview examination;
- End-stage renal disease (ESRD) related services;
- Individual and group medical nutrition therapy (MNT);
- Neurobehavioral status exam;
- Individual and group health and behavior assessment and intervention (HBAI);
- Subsequent hospital care;
- Subsequent nursing facility care;

- Individual and group kidney disease education (KDE);
- Individual and group diabetes self-management training (DSMT);
- Smoking cessation services;
- Alcohol and/or substance abuse and brief intervention services;
- Screening and behavioral counseling interventions in primary care to reduce alcohol misuse;
- Screening for depression in adults;
- Screening for sexually transmitted infections (STIs) and high intensity behavioral counseling
 (HIBC) to prevent STIs;
 - Intensive behavioral therapy for cardiovascular disease; and
 - Behavioral counseling for obesity.

In general, the practitioner at the distant site may be any of the following, provided that the practitioner is licensed under state law to furnish the service via a telecommunications system:

- Physician;
- Physician assistant (PA);
- Nurse practitioner (NP);
- Clinical nurse specialist (CNS);
- Nurse-midwife;
- Clinical psychologist;
- Clinical social worker;
- Registered dietitian or nutrition professional.

Practitioners furnishing Medicare telehealth services submit claims for telehealth services to the Medicare contractors that process claims for the service area where their distant site is located. Section 1834(m)(2)(A) of the Act requires that a practitioner who furnishes a telehealth service to an eligible telehealth individual be paid an amount equal to the amount that the practitioner would have been paid if the service had been furnished without the use of a telecommunications system. Distant site practitioners must submit the appropriate HCPCS procedure code for a covered professional telehealth service,

appended with the –GT (via interactive audio and video telecommunications system) or –GQ (via asynchronous telecommunications system) modifier. By reporting the –GT or –GQ modifier with a covered telehealth procedure code, the distant site practitioner certifies that the beneficiary was present at a telehealth originating site when the telehealth service was furnished. The usual Medicare deductible and coinsurance policies apply to the telehealth services reported by distant site practitioners.

Section 1834(m)(2)(B) of the Act provides for payment of a facility fee to the originating site. To be paid the originating site facility fee, the provider or supplier where the eligible telehealth individual is located must submit a claim with HCPCS code Q3014 (telehealth originating site facility fee), and the provider or supplier is paid according to the applicable payment methodology for that facility or location. The usual Medicare deductible and coinsurance policies apply to HCPCS code Q3014. By submitting HCPCS code Q3014, the originating site certifies that it is located in either a rural HPSA or non-MSA county or is an entity that participates in a federal telemedicine demonstration project that has been approved by (or receives funding from) the Secretary as of December 31, 2000 as specified in section 1834(m)(4)(C)(i)(III) of the Act.

As previously described, certain professional services that are commonly furnished remotely using telecommunications technology, but that do not require the patient to be present in-person with the practitioner when they are furnished, are covered and paid in the same way as services delivered without the use of telecommunications technology when the practitioner is in-person at the medical facility furnishing care to the patient. Such services typically involve circumstances where a practitioner is able to visualize some aspect of the patient's condition without the patient being present and without the interposition of a third person's judgment. Visualization by the practitioner can be possible by means of x-rays, electrocardiogram or electroencephalogram tracings, tissue samples, etc. For example, the interpretation by a physician of an actual electrocardiogram or electroencephalogram tracing that has been transmitted via telephone (that is, electronically, rather than by means of a verbal description) is a covered physician's service. These remote services are not Medicare telehealth services as defined under section 1834(m) of the Act. Rather, these remote services that utilize telecommunications technology are

considered physicians' services in the same way as services that are furnished in-person without the use of telecommunications technology; they are paid under the same conditions as in-person physicians' services (with no requirements regarding permissible originating sites), and should be reported in the same way (that is, without the –GT or –GQ modifier appended).

c. Geographic Criteria for Originating Site Eligibility

Section 1834(m)(4)(C)(i)(I) – (III) of the Act specifies three criteria for the location of eligible telehealth originating sites. One of these is for entities participating in federal telemedicine demonstration projects as of December 31, 2000, and the other two are geographic. One of the geographic criteria is that the site is located in a county that is not in an MSA and the other is that the site is located in an area that is designated as a rural HPSA under section 332(a)(1)(A) of the Public Health Service Act (PHSA) (42 U.S.C. 254e(a)(1)(A)). Section 332(a)(1)(A) of the PHSA provides for the designation of various types of HPSAs, but does not provide for "rural" HPSAs. In the absence of guidance in the PHSA, CMS has in the past interpreted the term "rural" under section 1834(m)(4)(C)(i)(I) to mean an area that is not located in an MSA. As such, the current geographic criteria for telehealth originating sites limits eligible sites to those that are not in an MSA.

To determine rural designations with more precision for other purposes, HHS and CMS have sometimes used methods that do not rely solely on MSA designations. For example, the Office of Rural Health Policy (ORHP) uses the Rural Urban Commuting Areas (RUCAs) to determine rural areas within MSAs. RUCAs are a census tract-based classification scheme that utilizes the standard Bureau of Census Urbanized Area and Urban Cluster definitions in combination with work commuting information to characterize all of the nation's census tracts regarding their rural and urban status and relationships. They were developed under a collaborative project between ORHP, the U.S. Department of Agriculture's Economic Research Service (ERS), and the WWAMI Rural Health Research Center (RHRC). A more comprehensive description is available at the USDA ERS website at: www.ers.usda.gov/data-products/rural-urban-commuting-area-codes/documentation.aspx#.UcsKfZwzZKE. The RUCA classification scheme contains 10 primary and 30 secondary codes. The primary code numbers (1 through

10) refer to the primary, or single largest, commuting share. Census tracts with RUCA codes of 4 through 10 refer to areas with a primary commuting share outside of a metropolitan area. In addition to counties that are not in an MSA, ORHP considers some census tracts in MSA counties to be rural. Specifically, census tracts with RUCA codes 4 through 10 are considered to be rural, as well as census tracts with RUCA codes 2 and 3 that are also at least 400 square miles and have a population density of less than 35 people per square mile.

We proposed to modify our regulations regarding originating sites to define rural HPSAs as those located in rural census tracts as determined by ORHP stating that by defining "rural" to include geographic areas located in rural census tracts within MSAs we would allow for the appropriate inclusion of additional HPSAs as areas for telehealth originating sites. We also noted that by adopting the more precise definition of "rural" for this purpose we would expand access to health care services for Medicare beneficiaries located in rural areas.

We also proposed to change our policy so that geographic eligibility for an originating site would be established and maintained on an annual basis, consistent with other telehealth payment policies. Absent this proposed change, the status of a geographic area's eligibility for telehealth originating site payment is effective at the same time as the effective date for changes in designations that are made outside of CMS. This proposed change would reduce the likelihood that mid-year changes to geographic designations would result in sudden disruptions to beneficiaries' access to services, unexpected changes in eligibility for established telehealth originating sites, and avoid the operational difficulties associated with administering mid-year Medicare telehealth payment changes. We proposed to establish geographic eligibility for Medicare telehealth originating sites for each calendar year based upon the status of the area as of December 31st of the prior calendar year.

Accordingly, we proposed to revise our regulations at §410.78(b)(4) to conform with both of these proposed policies.

The following is a summary of the comments we received regarding our proposed changes regarding geographic eligibility for serving as a Medicare telehealth originating site.

<u>Comment</u>: Commenters supported our proposal to modify the geographic criteria for originating site eligibility to define rural HPSAs as those located in rural census tracts, as determined by ORHP. In addition, commenters supported our proposal to establish and maintain geographic eligibility on an annual basis. Commenters noted that these modifications will:

- Expand access to health care services for Medicare beneficiaries by allowing some rural areas within MSAs to be eligible for Medicare telehealth services.
 - Provide greater clarity and consistency for those involved in telehealth.
- Allow for better continuity of care in rural areas by avoiding sudden disruptions to beneficiaries' access to telehealth services.
- Restore eligibility for some counties that were affected by the updated MSAs based on the
 2010 census.

Response: We appreciate the broad support for revising the geographic criteria for originating site eligibility and for establishing and maintaining geographic eligibility for an originating site on an annual basis. We are finalizing our CY 2014 proposals (1) to define rural HPSAs as those located in rural census tracts as determined by ORHP, and (2) to establish and maintain geographic eligibility for an originating site on an annual basis. Consistent with these proposals, we are also revising our regulations at §410.78(b)(4) to conform to these policies.

Comment: Commenters expressed concern that our proposed definition of a rural HPSA does not conform to the definition of a rural HPSA used for rural health clinic qualification, that is, a federally designated shortage area or a non-urbanized area, as defined by the U.S. Census Bureau. As a result, existing RHCs may be excluded from providing telehealth services to Medicare beneficiaries. To avoid this discrepancy, the commenters requested further expansion of the geographic criteria for originating site eligibility to include both non-urbanized areas, as defined by the U.S. Census Bureau, and those rural HPSAs located in rural census tracts, as determined by ORHP. A commenter also recommended that CMS work with the Health Resources and Services Administration (HRSA) to update all data with 2010 census information.

Other commenters recommended expansion of the geographic criteria for originating site to urban and suburban areas. A commenter recommended including sites that are located in (1) areas other than rural HPSAs and (2) counties that are included in MSAs. The commenter noted that beneficiaries in both urban and rural areas face significant barriers in accessing care, including access to certain specialists, such as gerontologists, and access to transportation.

A commenter noted that urban and suburban areas do not have appropriate access to acute stroke care, noting that 77 percent of U.S. counties did not have a hospital with neurological services. As a result of these and other barriers, only a small fraction of patients receive the treatment recommended by the latest scientific guidelines for acute stroke. The commenter concluded that our policy of limiting payment for telehealth services to those originating in rural areas has hampered the development of sufficient stroke consultation coverage and recommend eliminating the rural originating site requirement. Another commenter made similar points concerning cancer patients living in small urban areas without access to complex subspecialty care. A commenter proposed using RUCAs to determine eligible originating sites, to ensure greater access to telemedicine services.

Response: Telehealth originating sites are defined in section 1834(m)(4)(C) of the Act. Only a site that meets one of these requirements can qualify as an originating site:

- (1) Located in an area that is designated as a rural health professional shortage area under section 332(a)(1)(A) of the Public Health Service Act (42 U.S.C. 254e(a)(1)(A));
 - (2) Located in a county that is not included in a Metropolitan Statistical Area; or
- (3) From an entity that participates in a Federal telemedicine demonstration project that has been approved by (or receives funding from) the Secretary of Health and Human Services as of December 31, 2000.

Although RHCs are among the types of locations that are statutorily authorized to serve as originating sites for telehealth services, they also must meet the geographic requirements specified in the statute in order to serve as a telehealth originating site. While most RHCs would meet at least one of the geographic requirements to serve as a telehealth originating site, the separate statutory provisions that

establish geographic requirements for telehealth originating sites and for RHCs are sufficiently different that they do not necessarily overlap. We do not have the authority to waive the geographic telehealth requirements for those RHCs that do not meet any of the requirements to serve as an originating site.

Accordingly, we are not modifying our proposal to expand the scope of telehealth originating sites to include all RHCs, and we are finalizing our proposed regulation without change. We agree with the commenter that the data that are used to determine which areas are rural should be updated to reflect the 2010 census information.

Comment: Several commenters expressed that the complexity involved in determining geographic eligibility to serve as an originating site to provide telehealth services may deter providers from offering telehealth services. Commenters indicated that due to recent changes in the 2010 census there have been numerous changes in all rural designations. Commenters noted that RUCAs are a census tract-based classification scheme and there is no single source to determine one's census tract.

Commenters recommended that CMS provide an online tool to allow beneficiaries and providers to determine what specific geographic areas are eligible as telehealth originating sites. One commenter suggested simplifying the process in future years by considering using postal ZIP codes or ZIP+4.

Response: We share the commenters' concern that expanding the geographic definition of "rural" to include more telehealth originating sites has increased the complexity in determining the eligibility of a particular location to serve as an originating site. We are working with HRSA to develop a website tool to provide assistance to potential originating sites to determine their eligibility. As it becomes available, we will post further information about this on the CMS website at www.cms.gov/teleheath/.

Comment: A commenter expressed concern about the annual changes in coverage within census tracts that may occur under the proposal. The commenter recommended that CMS use its authority under the statute to avoid annual on/off/on/off coverage to reduce constant fluctuations in coverage of telehealth services. The commenter concluded that once covered for telehealth services, a beneficiary should not lose coverage because of accidental circumstances of geographic location and administrative designation.

Response: This regulation addresses which providers can qualify to be an originating site to furnish telehealth services. Beneficiaries do not have to meet specialized criteria for telehealth services. Beneficiaries who are covered under Medicare Part B can receive services on the list of Medicare telehealth services from providers that meet the criteria to serve as an originating site (and other criteria to furnish telehealth services). We recognize that beneficiaries may experience disruptions in service or challenges in accessing services when a provider that has been an originating site is not eligible in a future year. As discussed above, we believe our proposed policy mitigates the disruptions caused by mid-year changes in geographic status and expands the scope of providers eligible to serve as telehealth originating sites. However, as noted above, we believe it is necessary to use updated information regarding whether a site meets the statutory criteria for originating site eligibility. We do not believe we have authority to continue treating a site as a telehealth originating site if it ceases to meet the statutory criteria. Thus, we are finalizing the regulations regarding originating sites, as proposed to define rural HPSAs as those located in rural census tracts as determined by ORHP and to establish and maintain geographic eligibility for an originating site on an annual basis.

2. Adding Services to the List of Medicare Telehealth Services

As noted previously, in the December 31, 2002 **Federal Register** (67 FR 79988), we established a process for adding services to or deleting services from the list of Medicare telehealth services. This process provides the public with an ongoing opportunity to submit requests for adding services. We assign any request to make additions to the list of telehealth services to one of two categories. In the November 28, 2011 **Federal Register** (76 FR 73102), we finalized revisions to criteria that we use to review requests in the second category. The two categories are:

• <u>Category 1</u>: Services that are similar to professional consultations, office visits, and office psychiatry services that are currently on the list of telehealth services. In reviewing these requests, we look for similarities between the requested and existing telehealth services for the roles of, and interactions among, the beneficiary, the physician (or other practitioner) at the distant site and, if

necessary, the telepresenter. We also look for similarities in the telecommunications system used to deliver the proposed service; for example, the use of interactive audio and video equipment.

• Category 2: Services that are not similar to the current list of telehealth services. Our review of these requests includes an assessment of whether the service is accurately described by the corresponding code when delivered via telehealth and whether the use of a telecommunications system to deliver the service produces demonstrated clinical benefit to the patient. In reviewing these requests, we look for evidence indicating that the use of a telecommunications system in delivering the candidate telehealth service produces clinical benefit to the patient. Submitted evidence should include both a description of relevant clinical studies that demonstrate the service furnished by telehealth to a Medicare beneficiary improves the diagnosis or treatment of an illness or injury or improves the functioning of a malformed body part, including dates and findings, and a list and copies of published peer reviewed articles relevant to the service when furnished via telehealth. Our evidentiary standard of clinical benefit does not include minor or incidental benefits.

Some examples of clinical benefit include the following:

- Ability to diagnose a medical condition in a patient population without access to clinically appropriate in-person diagnostic services.
- Treatment option for a patient population without access to clinically appropriate in-person treatment options.
 - Reduced rate of complications.
- Decreased rate of subsequent diagnostic or therapeutic interventions (for example, due to reduced rate of recurrence of the disease process).
 - Decreased number of future hospitalizations or physician visits.
 - More rapid beneficial resolution of the disease process treatment.
 - Decreased pain, bleeding, or other quantifiable symptom.
 - Reduced recovery time.

Since establishing the process to add or remove services from the list of approved telehealth services, we have added the following to the list of Medicare telehealth services: individual and group HBAI services; psychiatric diagnostic interview examination; ESRD services with 2 to 3 visits per month and 4 or more visits per month (although we require at least 1 visit a month to be furnished in-person by a physician, CNS, NP, or PA to examine the vascular access site); individual and group MNT; neurobehavioral status exam; initial and follow-up inpatient telehealth consultations for beneficiaries in hospitals and SNFs; subsequent hospital care (with the limitation of one telehealth visit every 3 days); subsequent nursing facility care (with the limitation of one telehealth visit every 30 days); individual and group KDE; and individual and group DSMT (with a minimum of 1 hour of in-person instruction to ensure effective injection training), smoking cessation services; alcohol and/or substance abuse and brief intervention services; screening and behavioral counseling interventions in primary care to reduce alcohol misuse; screening for depression in adults; screening for sexually transmitted infections (STIs) and high intensity behavioral counseling (HIBC) to prevent STIs; intensive behavioral therapy for cardiovascular disease; and behavioral counseling for obesity.

Requests to add services to the list of Medicare telehealth services must be submitted and received no later than December 31 of each calendar year to be considered for the next rulemaking cycle. For example, requests submitted before the end of CY 2013 will be considered for the CY 2015 proposed rule. Each request for adding a service to the list of Medicare telehealth services must include any supporting documentation the requester wishes us to consider as we review the request. Because we use the annual PFS rulemaking process as a vehicle for making changes to the list of Medicare telehealth services, requestors should be advised that any information submitted is subject to public disclosure for this purpose. For more information on submitting a request for an addition to the list of Medicare telehealth services, including where to mail these requests, we refer readers to the CMS website at www.cms.gov/telehealth/.

3. Submitted Requests and Other Additions to the List of Telehealth Services for CY 2014

We received a request in CY 2012 to add online assessment and E/M services as Medicare telehealth services effective for CY 2014. The following presents a discussion of this request, and our proposals for additions to the CY 2014 telehealth list.

a. Submitted Requests

The American Telemedicine Association (ATA) submitted a request to add CPT codes 98969 (Online assessment and management service provided by a qualified nonphysician health care professional to an established patient, guardian, or health care provider not originating from a related assessment and management service provided within the previous 7 days, using the Internet or similar electronic communications network) and 99444 (Online evaluation and management service provided by a physician to an established patient, guardian, or health care provider not originating from a related E/M service provided within the previous 7 days, using the Internet or similar electronic communications network) to the list of Medicare telehealth services.

As we explained in the CY 2008 PFS final rule with comment period (72 FR 66371), we assigned a status indicator of "N" (Non-covered service) to these services because: (1) these services are non-face-to-face; and (2) the code descriptor includes language that recognizes the provision of services to parties other than the beneficiary and for whom Medicare does not provide coverage (for example, a guardian). Under section 1834(m)(2)(A) of the Act, Medicare pays the physician or practitioner furnishing a telehealth service an amount equal to the amount that would have been paid if the service was furnished without the use of a telecommunications system. Because CPT codes 98969 and 99444 are currently noncovered, there would be no Medicare payment if these services were furnished without the use of a telecommunications system. Since these codes are noncovered services for which no payment may be made under Medicare, we did not propose to add online evaluation and management services to the list of Medicare Telehealth Services for CY 2014.

b. Other Additions

Under our existing policy, we add services to the telehealth list on a category 1 basis when we determine that they are similar to services on the existing telehealth list with respect to the roles of, and

interactions among, the beneficiary, physician (or other practitioner) at the distant site and, if necessary, the telepresenter. As we stated in the CY 2012 proposed rule (76 FR 42826), we believe that the category 1 criteria not only streamline our review process for publically requested services that fall into this category, the criteria also expedite our ability to identify codes for the telehealth list that resemble those services already on this list.

For CY 2013, CMS finalized a payment policy for new CPT code 99495 (Transitional care management services with the following required elements: Communication (direct contact, telephone, electronic) with the patient and/or caregiver within 2 business days of discharge medical decision making of at least moderate complexity during the service period face-to-face visit, within 14 calendar days of discharge) and CPT code 99496 (Transitional care management services with the following required elements: Communication (direct contact, telephone, electronic) with the patient and/or caregiver within 2 business days of discharge medical decision making of high complexity during the service period face-to-face visit, within 7 calendar days of discharge). These services are for a patient whose medical and/or psychosocial problems require moderate or high complexity medical decision making during transitions in care from an inpatient hospital setting (including acute hospital, rehabilitation hospital, long-term acute care hospital), partial hospitalization, observation status in a hospital, or skilled nursing facility/nursing facility, to the patient's community setting (home, domiciliary, rest home, or assisted living). Transitional care management is comprised of one face-to-face visit within the specified time frames following a discharge, in combination with non-face-to-face services that may be performed by the physician or other qualified health care professional and/or licensed clinical staff under his or her direction.

We believe that the interactions between the furnishing practitioner and the beneficiary described by the required face-to-face visit component of the transitional care management (TCM) services are sufficiently similar to services currently on the list of Medicare telehealth services for these services to be added under category 1. Specifically, we believe that the required face-to-face visit component of TCM services is similar to the office/outpatient evaluation and management visits described by CPT codes 99201-99205 and 99211-99215. We note that like certain other non-face-to-face PFS services, the other

components of the TCM service are commonly furnished remotely using telecommunications technology, and do not require the patient to be present in-person with the practitioner when they are furnished. As such, we do not need to consider whether the non-face-to-face aspects of the TCM service are similar to other telehealth services. Were these components of the TCM services separately billable, they would not need to be on the telehealth list to be covered and paid in the same way as services delivered without the use of telecommunications technology. Therefore, we proposed to add CPT codes 99495 and 99496 to the list of telehealth services for CY 2014 on a category 1 basis. Consistent with this proposal, we revised our regulations at §410.78(b) and §414.65(a)(1) to include TCM services as Medicare telehealth services.

4. Telehealth Frequency Limitations

The ATA asked that we remove the telehealth frequency limitation for subsequent nursing facility services reported by CPT codes 99307 through 99310. Subsequent nursing facility services were added to the list of Medicare telehealth services in the CY 2011 PFS final rule (75 FR 73317 through 73318), with a limitation of one telehealth subsequent nursing facility care service every 30 days. In the CY 2011 PFS final rule (75 FR 73615) we noted that, as specified in our regulation at §410.78(e)(2), the federally mandated periodic SNF visits required under §483.40(c) could not be furnished through telehealth.

The ATA requested that the frequency limitation be removed due to "recent federal telecommunications policy changes" and newly available information from recent studies. Specifically, the ATA pointed to the Federal Communications Commission (FCC) pilot funding of a program to facilitate the creation of a nationwide broadband network dedicated to health care, connecting public and private non-profit health care providers in rural and urban locations, and a series of studies that demonstrated the value to patients of telehealth technology.

In considering this request, we began with the analysis contained in the CY 2011 proposed rule (75 FR 73318), when we proposed to add SNF subsequent care, to the list of Medicare telehealth services. We discussed our complementary commitments to ensuring that SNF residents, given their potential clinical acuity, continue to receive in-person visits as appropriate to manage their complex care and to make sure that Medicare pays only for medically reasonable and necessary care. To meet these

commitments, we believed it was appropriate to limit the provision of subsequent nursing facility care services furnished through telehealth to once every 30 days.

We then reviewed the publicly available information regarding both the FCC pilot program and the ATA-referenced studies in light of the previously stated commitments to assess whether these developments warrant a change in 30-day frequency limitation policy. Based on our review of the FCC demonstration project and the studies referenced in the request, we found no information regarding the relative clinical benefits of SNF subsequent care when furnished via telehealth more frequently than once every 30 days. We did note that the FCC information reflected an aim to improve access to medical specialists in urban areas for rural health care providers, and that medical specialists in urban areas can continue to use the inpatient telehealth consultation HCPCS G-codes (specifically G0406, G0407, G0408, G0425, G0426, or G0427) when reporting medically reasonable and necessary consultations furnished to SNF residents via telehealth without any frequency limitation.

We also reviewed the studies referenced by the ATA to assess whether they provided evidence that more frequent telehealth visits would appropriately serve this particular population given the potential medical acuity and complexity of patient needs. We did not find any such evidence in the studies. Three of the studies identified by the ATA were not directly relevant to SNF subsequent care services. One of these focused on using telehealth technology to treat patients with pressure ulcers after spinal cord injuries. The second focused on the usefulness of telehealth technology for patients receiving home health care services. A third study addressed the use of interactive communication technology to facilitate the coordination of care between hospital and SNF personnel on the day of hospital discharge. The ATA also mentioned a peer-reviewed presentation delivered at its annual meeting related to SNF patient care, suggesting that the presentation demonstrated that telehealth visits are better for SNF patients than in-person visits to emergency departments or, in some cases, visits to physician offices. Although we did not have access to the full presentation it does not appear to address subsequent nursing facility services, so we do not believe this is directly relevant to the clinical benefit of SNF subsequent care furnished via telehealth. More importantly, none of these studies addresses the concerns we have

expressed about the possibility that nursing facility subsequent care visits furnished too frequently through telehealth rather than in-person could compromise care for this potentially acute and complex patient population.

We remain committed to ensuring that SNF inpatients receive appropriate in-person visits and that Medicare pays only for medically reasonable and necessary care. We are not persuaded by the information submitted by the ATA that it would be beneficial or advisable to remove the frequency limitation we established for SNF subsequent care when furnished via telehealth. Because we want to ensure that nursing facility patients with complex medical conditions have appropriately frequent, medically reasonable and necessary encounters with their admitting practitioner, we continue to believe that it is appropriate for some subsequent nursing facility care services to be furnished through telehealth. At the same time, because of the potential acuity and complexity of SNF inpatients, we remain committed to ensuring that these patients continue to receive in-person, hands-on visits as appropriate to manage their care. Therefore, we did not propose any changes to the limitations regarding SNF subsequent care services furnished via telehealth for CY 2014.

The following is summary of the comments we received regarding adding services to the list of Medicare telehealth services.

Comment: All commenters expressed support for our proposals to add transitional care management (CPT codes 99495 and 99496) to the list of Medicare telehealth services for CY 2014. A commenter suggested that CMS allow the required E/M visit component of the two CPT codes to be delivered via telehealth.

Response: We appreciate the support for the proposed additions to the list of Medicare telehealth services. In response to the commenter asking that the required E/M visit component be allowed to be furnished via telehealth, adding TCM CPT codes 99495 and 99496 to the list of Medicare telehealth services allows the E/M portion of these services to be furnished via telehealth. After consideration of the public comments received, we are finalizing our CY 2014 proposal to add TCM CPT codes 99495 and 99496 to the list of telehealth services for CY 2014 on a category 1 basis.

<u>Comment</u>: Another commenter recommended that the originating site be required to conduct a physical examination of a patient's mental and physical condition following a care transaction, and transmit the results to the consulting physician before or during the telehealth session, as a condition for coverage of transitional care management services provided via telehealth.

Response: Concerning the conduct of a physical examination, nothing would preclude such an in person, face-to-face examination from occurring at the originating site; and the TCM codes describe communication between practitioners, when appropriate. We are not adopting this recommendation as we do not believe there is a reason to treat these new additions to the list of telehealth services differently than services already on the list.

<u>Comment</u>: A commenter asked whether providing transitional care management via telehealth applies to services furnished in private homes and assisted living facilities.

Response: No, in furnishing TCM services as telehealth services, all other conditions for telehealth services still apply. In addition to geographic criteria, the statutory criteria for eligible originating sites include only certain types of locations specified in section 1834(m)(4)(C)(ii) of the Act, and those do not include private homes and assisted living facilities.

<u>Comment</u>: A commenter supported our decision not to remove the telehealth frequency limitation for subsequent nursing facility services reported by CPT codes 99307 through 99310. The commenter noted that telehealth occupational therapy services are just beginning to be provided and evaluated, and indicated that it is important to ensure that care for the acute and complex patients found in SNFs is not compromised, regardless of the mode used to provide services.

Another commenter disagreed with our determination that there is no relative clinical benefit from allowing SNF services to be provided via telehealth more than once every 30 days. The commenter indicated that CMS recently issued Survey and Certification Memo 13-35-NH, which put additional emphasis on the survey process for managing behavioral or psychological symptoms of dementia and limiting the use of antipsychotic medications in SNFs. The commenter concluded that having this medical/behavioral evaluation performed by the primary care provider or a psychiatrist using telehealth

could help reduce the need to transfer the patient to the emergency department, which could possibly exacerbate dementia symptoms.

A commenter stated that the frequency limitation can result in additional unnecessary transports for office or emergency department visits, additional opportunities for patient injury, and significant transportation costs especially for the immobile and disabled patient. In light of the evolving mobile health technologies, robotics, and miniaturization of telecommunications tools and medical devices, as well as the increasing complexity and co-morbidities of SNF patients, the commenter recommended setting the limit at one visit per 10 days.

A commenter suggested that subsequent nursing facility care services furnished through telehealth should not be limited to one service every 30 days, as long as the federally mandated SNF visits are conducted on an in-person basis.

Response: We appreciate the comment in support of maintaining the 30-day limit. Commenters opposed to the 30-day limit offered no clinically persuasive evidence to support their positions. Survey and Certification Memo 13-35-NH addresses dementia care in nursing homes and unnecessary drug use. The memo does not address telehealth services, and does not represent clinical evidence supporting removal of the telehealth frequency limitation for subsequent nursing facility services. Therefore, we are maintaining the 30-day frequency limitation for subsequent nursing facility services due to the absence of evidence regarding the relative clinical benefits of SNF subsequent care when furnished via telehealth more frequently than once every 30 days, and to ensure that SNF patients continue to receive in-person, hands-on visits as appropriate to manage their care.

Comment: A commenter urged CMS to reconsider its decision to not include CPT codes 98969 (Online assessment and management service provided by a qualified nonphysician health care professional to an established patient, guardian, or health care provider not originating from a related assessment and management service provided within the previous 7 days, using the Internet or similar electronic communications network) and 99444 (Online evaluation and management service provided by a physician to an established patient, guardian, or health care provider not originating from a related E/M

service provided within the previous 7 days, using the Internet or similar electronic communications network) on the list of Medicare telehealth services. The commenter noted that such services can serve as a valuable preventive benefit in the treatment and care of Medicare beneficiaries; that such services are often are unavailable to beneficiaries who reside in very rural areas; and that telehealth services should be expanded in view of the increasing number of beneficiaries and the projected physician shortage.

Response: As noted previously, we did not propose to add the subject codes to the list of telehealth services because they are noncovered services for which no payment may be made under Medicare. Accordingly we are finalizing our proposal.

In summary, after consideration of the comments we received we are finalizing the changes to our regulation at §410.78 to add "transitional care management" to the list of services in paragraph (b) as proposed.

We remind all interested stakeholders that we are currently soliciting public requests to add services to the list of Medicare telehealth services. To be considered during PFS rulemaking for CY 2015, these requests must be submitted and received by December 31, 2013, or the close of the comment period for this final rule with comment period. Each request to add a service to the list of Medicare telehealth services must include any supporting documentation the requester wishes us to consider as we review the request. For more information on submitting a request for an addition to the list of Medicare telehealth services, including where to mail these requests, we refer readers to the CMS website at www.cms.gov/telehealth/.

5. Telehealth Originating Site Facility Fee Payment Amount Update

Section 1834(m)(2)(B) of the Act establishes the payment amount for the Medicare telehealth originating site facility fee for telehealth services provided from October 1, 2001, through December 31 2002, at \$20.00. For telehealth services provided on or after January 1 of each subsequent calendar year, the telehealth originating site facility fee is increased by the percentage increase in the MEI as defined in section 1842(i)(3) of the Act. The MEI increase for 2014 is 0.8 percent. Therefore, for CY 2014, the payment amount for HCPCS code Q3014 (Telehealth originating site facility fee) is

80 percent of the lesser of the actual charge or \$24.63. The Medicare telehealth originating site facility fee and MEI increase by the applicable time period is shown in Table 46.

TABLE 46: The Medicare Telehealth Originating Site Facility Fee and MEI Increase by the Applicable Time Period

Facility Fee	MEI	Period
	Increase	
\$20.00	N/A	10/01/2001 - 12/31/2002
\$20.60	3.0%	01/01/2003 - 12/31/2003
\$21.20	2.9%	01/01/2004 - 12/31/2004
\$21.86	3.1%	01/01/2005 - 12/31/2005
\$22.47	2.8%	01/01/2006 - 12/31/2006
\$22.94	2.1%	01/01/2007 - 12/31/2007
\$23.35	1.8%	01/01/2008 - 12/31/2008
\$23.72	1.6%	01/01/2009 - 12/31/2009
\$24.00	1.2%	01/01/2010 - 12/31/2010
\$24.10	0.4%	01/01/2011 - 12/31/2011
\$24.24	0.6%	01/01/2012 - 12/31/2012
\$24.43	0.8%	01/01/2013 - 12/31/2013
\$24.63	0.8%	01/01/2014 - 12/31/2014

I. Therapy Caps

1. Outpatient Therapy Caps for CY 2014

Section 1833(g) of the Act applies annual, per beneficiary, limitations on expenses that can be considered as incurred expenses for outpatient therapy services under Medicare Part B, commonly referred to as "therapy caps." There is one therapy cap for outpatient occupational therapy (OT) services and another separate therapy cap for physical therapy (PT) and speech-language pathology (SLP) services combined.

Until October 1, 2012, the therapy caps applied to all outpatient therapy services except those under section 1833(a)(8)(B) of the Act, which describes services furnished by a hospital or another entity under an arrangement with a hospital. For convenience, we will refer to the exemption from the caps for services described under section 1833(a)(8)(B) of the Act as the "outpatient hospital services exemption." Section 3005(b) of the MCTRJCA added section 1833(g)(6) of the Act to temporarily suspend the outpatient hospital services exemption, thereby requiring that the therapy caps apply to services described under section 1833(a)(8)(B) of the Act from October 1, 2012 to December 31, 2012 for services furnished beginning January 1, 2012. This broadened application of the therapy caps was extended through December 31, 2013, by section 603(a) of the ATRA. In addition, section 603(b) of the ATRA amended section 1833(g)(6) of the Act to specify that during CY 2013, for outpatient therapy services paid under section 1834(g) of the Act (those furnished by a CAH), we must count towards the therapy caps the amount that would be payable for the services under Medicare Part B if the services were paid as outpatient therapy services under section 1834(k)(1)(B) of the Act, which describes payment for outpatient therapy services furnished by hospitals and certain other entities, instead of as CAH outpatient therapy services under section 1834(g) of the Act. Payment for outpatient therapy services under section 1834(k)(1)(B) of the Act is made at 80 percent of the lesser of the actual charge for the services or the applicable fee schedule amount as defined in section 1834(k)(3) of the Act. Section 1834(k)(3) of the Act defines applicable fee schedule to mean the payment amount determined under a fee schedule established under section 1848 of the Act, which refers to the PFS, or an amount under a fee schedule for comparable

services as the Secretary specifies. The PFS is the applicable fee schedule to be used as the payment basis under section 1834(k)(3) of the Act. Section 603(b) of the ATRA specified that nothing in the amendments to section 1833(g)(6) of the Act "shall be construed as changing the method of payment for outpatient therapy services under 1834(g) of the Act."

Since CY 2011, a therapy multiple procedure payment reduction (MPPR) policy has applied to the second and subsequent "always therapy" services billed on the same date of service for one patient by the same practitioner or facility under the same NPI. Prior to April 1, 2013, the therapy MPPR reduced the practice expense portion of office-based services by 20 percent and reduced the practice expense portion of institutional-based services by 25 percent. As of April 1, 2013, section 633(a) of the ATRA amended sections 1848(b)(7) and 1834(k) of the Act to increase the therapy MPPR to 50 percent for all outpatient therapy services furnished in office-based and institutional settings. (For more information on the MPPR and its history, see section II.C.4 of this final rule with comment period.)

Section 1833(g) of the Act applies the therapy caps to incurred expenses for outpatient therapy services on a calendar year basis, and section 603(b) of the ATRA requires that we accrue toward the therapy caps a proxy value for a beneficiary's incurred expenses for outpatient therapy services furnished by a CAH during CY 2013. Since payment for outpatient therapy services under section 1834(k)(1)(B) of the Act is made at the PFS rate and includes any applicable therapy MPPR, the proxy amounts accrued toward the caps for therapy services furnished by a CAH also reflect any applicable therapy MPPR.

We believe that this is consistent with the statutory amendments made by the ATRA. Including the therapy MPPR in calculating incurred expenses for therapy services furnished by CAHs treats CAH services consistently with services furnished in other applicable settings. Therefore, therapy services furnished by CAHs during CY 2013 count towards the therapy caps using the amount that would be payable under section 1834(k)(1)(B) of the Act, which includes an applicable MPPR. For a list of the "always therapy" codes subject to the therapy MPPR policy, see Addendum H of this final rule with comment period.

The therapy cap amounts under section 1833(g) of the Act are updated each year based on the MEI. Specifically, the annual caps are calculated by updating the previous year's cap by the MEI for the upcoming calendar year and rounding to the nearest \$10 as specified in section 1833(g)(2)(B) of the Act. Increasing the CY 2013 therapy cap of \$1,900 by the CY 2014 MEI of 0.8 percent, results in a therapy cap amount for CY 2014 of \$1,920.

An exceptions process for the therapy caps has been in effect since January 1, 2006. Originally required by section 5107 of the Deficit Reduction Act of 2005 (DRA), which amended section 1833(g)(5) of the Act, the exceptions process for the therapy caps has been continuously extended several times through subsequent legislation (MIEA-TRHCA, MMSEA, MIPPA, the Affordable Care Act, MMEA, TPTCCA, and MCTRJCA). Last amended by section 603(a) of the ATRA, the Agency's current authority to provide an exceptions process for therapy caps expires on December 31, 2013. After expenses incurred for the beneficiary's services for the year have exceeded the therapy caps, therapy suppliers and providers use the KX modifier on claims for services to request an exception to the therapy caps. By use of the KX modifier, the therapist is attesting that the services above the therapy caps are reasonable and necessary and that there is documentation of medical necessity for the services in the beneficiary's medical record.

Under section 1833(g)(5)(C) of the Act, which was added by the MCTRJCA and extended through 2013 by the ATRA, we are required to apply a manual medical review process to therapy claims when a beneficiary's incurred expenses exceed a threshold amount of \$3,700. There are two separate thresholds of \$3,700, just as there are two therapy caps, and incurred expenses are counted towards the thresholds in the same manner as the caps. Under the statute, the required application of the manual medical review process expires December 31, 2013. For information on the manual medical review process, go to www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medical-Review/TherapyCap.html.

2. Application of Therapy Caps to Services furnished by CAHs

Section 4541 of the BBA amended section 1833(g) of the Act to create the therapy caps discussed above. This BBA provision applied the therapy caps to outpatient therapy services described at section 1861(p) of the Act except for the outpatient therapy services described in section 1833(a)(8)(B) of the Act. Section 1833(a)(8)(B) of the Act refers to therapy services furnished by a hospital to an outpatient; to services furnished to a hospital inpatient who has exhausted, or is not entitled to, benefits under Part A; and to these same services when furnished by an entity under arrangements with a hospital. Payment for the services described under section 1833(a)(8)(B) of the Act is made under section 1834(k)(1)(B) of the Act.

Section 4201 of the BBA amended section 1820 of the Act to require a process for establishment of CAHs. Payment for CAH outpatient services is described under section 1834(g) of the Act.

When we proposed language to implement the BBA provision establishing therapy caps in the CY 1999 PFS proposed rule, we indicated in the preamble that the therapy caps do not apply to therapy services furnished directly or under arrangements by a hospital or CAH to an outpatient or to an inpatient who is not in a covered Part A stay (63 FR 30818, 30858). We included a similar statement in the preamble to the final rule; however, we did not include the same reference to CAHs in that sentence in the CY 1999 PFS final rule with comment period (63 FR 58814, 58865). In the CY 1999 PFS final rule with comment period, we also stated generally that the therapy caps apply only to items and services furnished by nonhospital providers and therapists (63 FR 58865). In the CY 1999 proposed rule, we proposed to include provisions at §410.59(e)(3) and §410.60(e)(3) to describe, respectively, the outpatient therapy services that are exempt from the statutory therapy caps for outpatient OT services, and for outpatient PT and SLP services combined. Specifically, in the CY 1999 PFS proposed rule, we proposed to add the following regulatory language for OT and for PT at §410.59(e)(3) and §410.60(e)(3): "For purposes of applying the limitation, outpatient [occupational therapy/physical therapy] excludes services furnished by a hospital or CAH directly or under arrangements" (63 FR 30880). However, in the CY 1999 PFS final rule with comment period, the phrase "or CAH" was omitted from the final regulation text for OT in §410.59(e)(3), but was included in the final regulation text for PT in §410.60(e)(3). We note that for

purposes of the therapy cap, outpatient PT services under our regulation at §410.60 include outpatient SLP services described under §410.62. As such, SLP services are included in the references to PT under §410.60. Although the rulemaking history and regulations appear inconclusive as to whether outpatient therapy services furnished by CAHs were intended to be subject to the therapy caps between January 1, 1999 and October 1, 2012, we believe that we inadvertently omitted the phrase "or CAH" in the CY 1999 final regulation for the occupational therapy cap. Moreover, we have consistently excluded all outpatient therapy services furnished by CAHs from the therapy caps over this time frame, whether the services were PT, SLP, or OT.

Accordingly, from the outset of the therapy caps under section 1833(g) of the Act, therapy services furnished by CAHs have not been subject to the therapy caps. Thus, CAHs have not been required to use the exceptions process (including the KX modifier and other requirements) when furnishing medically necessary therapy services above the therapy caps; and therapy services furnished by CAHs above the threshold amounts have not been subject to the manual medical review process. Similarly, until section 603(b) of the ATRA amended the statute to specify the amount that must be counted towards the therapy caps and thresholds for outpatient therapy services furnished by CAHs in CY 2013, we did not apply towards the therapy caps or thresholds any amounts for therapy services furnished by CAHs. Therefore, we have consistently interpreted the statutory exclusion for outpatient therapy services furnished by hospital outpatient departments also to apply to CAHs and implemented the therapy caps accordingly.

As noted above, section 3005(b) of the MCTRJCA temporarily suspended the outpatient hospital services exemption from October 1, 2012 through December 31, 2012 (which has subsequently been extended through December 31, 2013 by the ATRA). As a result, from October 1, 2012 to the present, CAH services have been treated differently than services furnished in other outpatient hospital settings. In implementing this change required by the MCTRJCA, we had reason to assess whether, as a result of the amendment, the therapy caps should be applied to outpatient therapy services furnished by CAHs. We concluded that the MCTRJCA amendment did not make the therapy caps applicable to services

furnished by CAHs for which payment is made under section 1834(g) of the Act because it affected only the outpatient hospital services described under section 1833(a)(8)(B) of the Act for which payment is made under section 1834(k)(1)(B) of the Act. With the enactment in section 603(b) of the ATRA of specific language requiring us to count amounts towards the therapy caps and thresholds for services furnished by CAHs, we again had reason to assess whether the therapy caps apply to services furnished by CAHs. We concluded that the ATRA amendment did not explicitly make the therapy caps applicable to services furnished by CAHs, but directed us to count CAH services towards the caps. However, after reflecting on the language of section 1833(g) of the Act, we have concluded based upon the language of the Act that the therapy caps should be applied to outpatient therapy services furnished by CAHs.

To explain further, under section 1833(g)(1) and (3) of the Act, the therapy caps are made applicable to all services described under section 1861(p) of the Act except those described under the outpatient hospital services exemption. Section 1861(p) of the Act establishes the benefit category for outpatient PT, SLP and OT services, (expressly for PT services and, through section 1861(ll)(2) of the Act, for outpatient SLP services and, through section 1861(g) of the Act, for outpatient OT services). Section 1861(p) of the Act defines outpatient therapy services in the three disciplines as those furnished by a provider of services, a clinic, rehabilitation agency, or a public health agency, or by others under an arrangement with, and under the supervision of, such provider, clinic, rehabilitation agency, or public health agency to an individual as an outpatient; and those furnished by a therapist not under arrangements with a provider of services, clinic, rehabilitation agency, or a public health agency. As such, section 1861(p) of the Act defines outpatient therapy services very broadly to include those furnished by providers and other institutional settings, as well as those furnished in office settings. Under section 1861(u) of the Act, a CAH is a "provider of services." As such, unless the outpatient therapy services furnished by a CAH fit within the outpatient hospital services exemption under section 1833(a)(8)(B) of the Act, the therapy caps would be applicable to PT, SLP, OT services furnished by a CAH. As noted above, section 1833(a)(8)(B) of the Act describes only outpatient therapy services for which payment is made under section 1834(k) of the Act. Payment for CAH services is made under section 1834(g) of the

Act. Thus, the outpatient hospital services exemption to the therapy caps under section 1833(a)(8)(B) of the Act does not apply, and the therapy caps are applicable, to outpatient therapy services furnished by a CAH.

However, we recognize that our current regulation specifically excludes PT and SLP services furnished by CAHs from the therapy caps, and our consistent practice since 1999 has been to exclude PT, SLP and OT services furnished by CAHs from the therapy caps. As such, in order to apply the therapy caps and related policies to services furnished by CAHs for CY 2014 and subsequent years, we believe we would need to revise our regulations.

We proposed to apply the therapy cap limitations and related policies to outpatient therapy services furnished by a CAH beginning on January 1, 2014. In the proposed rule, we noted that not only do we believe this is the proper statutory interpretation, but we also believe it is the appropriate policy. Under the existing regulations, with the suspension of the outpatient hospital services exemption through 2013, the therapy caps apply to outpatient therapy services paid under Medicare Part B and furnished in all applicable settings except CAHs. We believe that outpatient therapy services furnished by a CAH should be treated consistently with outpatient therapy services furnished in all other settings. Therefore, we proposed to revise the therapy cap regulation at §410.60(e)(3) to remove the exemption for services furnished by a CAH and make conforming amendments.

CAH outpatient therapy services are distinct from other outpatient therapy services in that outpatient therapy services furnished in office-based or other institutional settings are paid at the rates contained in the PFS, whereas CAHs are paid for outpatient therapy services under the methodology described under section 1834(g) of the Act. Because the CAH reasonable cost-based payment amounts are reconciled at cost reporting year-end, and are different from the fee schedule-based payments for other outpatient therapy services, it might have been difficult to identify the amounts that we should have accrued towards the therapy caps for services furnished by CAHs. Therefore, prior to 2013, not only did CMS not apply any caps to services provided by a CAH, but also did not count CAH services towards the caps. However, the ATRA amended the statute to require for outpatient therapy services furnished by

CAHs during 2013 that we count towards the caps and the manual medical review thresholds the amount that would be payable for the services under Medicare Part B as if the services were paid as outpatient therapy services under section 1834(k)(1)(B) of the Act instead of as CAH services under section 1834(g) of the Act. We proposed to continue this methodology of counting the amount payable under section 1834(k)(1)(B) of the Act towards the therapy cap and threshold for services furnished by CAHs in CY 2014 and subsequent years.

We recognize that the outpatient hospital services exemption is suspended under current law only through December 31, 2013. If this provision is not extended, with our proposal to apply the therapy caps to services furnished by CAHs, effective January 1, 2014, therapy services furnished by CAHs would be treated differently than services furnished in other outpatient hospital settings. We recognize that the exceptions and manual medical review processes expire on December 31, 2013, and we would apply those polices to therapy services furnished by a CAH only if they are extended by statute. The exceptions process described above, including use of the KX modifier to attest to the medical necessity of therapy services above the caps and other requirements, if extended by legislation, would apply for services furnished by a CAH in the same way that it applies to outpatient therapy services furnished by other facilities (except for any that are expressly exempted). Similarly, the manual medical review process for claims that exceed the \$3,700 thresholds, if extended by legislation, would apply to therapy services furnished by a CAH in the same way that they apply for outpatient therapy services furnished by certain other facilities.

We proposed to amend the regulations establishing the conditions for PT, OT, and SLP services by removing the exemption of CAH services from the therapy caps and specifying that the therapy caps apply to such services. Specifically, we proposed to amend the regulations, which pertain to the OT therapy cap and the combined PT and SLP therapy cap, respectively, by including paragraph (e)(1)(iv) under §410.59 and (e)(1)(iv) under §410.60 to specify that (occupational/physical) therapy services furnished by a CAH directly or under arrangements shall be counted towards the annual limitation on incurred expenses as if such services were paid under section 1834(k)(1)(B) of the Act. We also proposed

to add new paragraph (e)(2)(v) to §410.59 and (e)(2)(vi) to §410.60. These new paragraphs would expressly include outpatient (occupational/physical) therapy services furnished by a CAH directly or under arrangements under the description of services to which the annual limitation applies. Further, we proposed to amend the regulation at §410.60(e)(3), which currently excludes services furnished by a CAH from the therapy cap for PT and SLP services, to remove the phrase "or CAH."

The following is a summary of the comments we received regarding the proposal to apply the therapy cap limitations and related policies to outpatient therapy services furnished by a CAH beginning on January 1, 2014. We received many comments from professional therapy associations, hospital associations, health systems, nonprofit health care organizations, and specialty provider groups regarding our proposal, all of which opposed the application of the therapy caps to CAH services. A summary of the reasons stated for opposition follow.

Comment: Most of the comments we received argued that due to the critical role that CAHs play in furnishing healthcare services in underserved or rural areas, imposing the financial and administrative burden of the therapy caps on CAHs would result in Medicare beneficiaries having fewer, if any, options for accessing needed therapy services in CAH service areas. A few commenters noted that Congress established the CAH designation in order to make health care services accessible to Medicare beneficiaries in rural areas who would otherwise be unable to access hospital services and argued that our proposed policy would be contrary to Congress's goal. Commenters noted that those most affected by this policy are beneficiaries living in rural areas who are on average older, sicker, poorer, and more geographically isolated compared to individuals in urban areas. Commenters pointed out that in rural or underserved areas therapy services enable beneficiaries to recover and reconstruct their lives after experiencing medical emergencies such as a stroke. Commenters also noted that if a therapy cap exceptions process is not in place, our proposed policy would result in Medicare beneficiaries either being financially liable for additional services or foregoing medically necessary services. Several commenters stated that this proposal would place an unnecessary burden on CAHs since it was unlikely that applying

the therapy caps to CAHs would result in significant cost savings or reduce unnecessary care; and some even said that our proposed policy would actually increase costs for the Medicare program.

Response: After reassessing our interpretation of section 1833(g) of the Act under our proposed policy, we continue to conclude that the proper statutory interpretation would be to apply the therapy caps and related provisions to outpatient therapy services furnished by CAHs. We agree with commenters that CAHs provide important access to medically necessary therapy services for Medicare beneficiaries; however, we do not believe that application of the therapy caps and related policies to services furnished by CAHs will lead to significant new impediments for Medicare beneficiaries. Under our proposed policy, CAHs would be subject to the therapy caps, as well as any potential extension of the therapy caps exceptions and manual medical review processes, in the same manner as other providers of therapy services except for those that are specifically exempted by statute from application of the caps and related provisions. As such, the therapy caps and related provisions would affect therapy services furnished by a CAH and other providers of such services in a comparable degree. We also do not believe that applying the therapy caps to services furnished by CAHs would negatively affect the ability of CAHs to furnish therapy services to Medicare beneficiaries. We believe that any increase in the administrative burden presented by the therapy caps and, if extended by legislation, the exceptions and manual medical review processes, will be only minor. As we explained in the proposed rule and noted above, we believe the proper interpretation of the statute requires us to apply the therapy caps to services furnished by CAHs.

<u>Comment</u>: We received a few comments stating that the drawbacks of the therapy caps would be exacerbated by applying this policy to additional provider settings. Most of these commenters argued that the therapy cap has been problematic since its inception. One

commenter suggested that, instead of applying the therapy caps to CAHs, we should develop an alternative policy to replace the cap.

Response: The therapy caps are mandated by statute and we do not have authority to repeal the caps. As such, we will continue to apply the statutorily mandated therapy caps as specified under the statute which, as we have discussed above, includes applying the therapy caps policy to CAHs.

Comment: We received several comments stating that our current policies, in addition to our proposed regulations, overly control the utilization of therapy services. Most of these commenters noted that under §409.17 of the regulations, therapy services are required to be ordered by a physician prior to a qualified professional initiating a plan of care, and these commenters argued that the requirement for an order can control utilization of therapy services in CAHs. One commenter noted that the direct supervision policy expressed in the CY 2014 OPPS proposed rule coupled with our proposal would cause services in CAHs to be overregulated.

Response: We disagree with commenters that CAHs are overregulated with respect to outpatient therapy services. We do not believe our proposed policy overregulates CAH services as compared to other providers of therapy services. We also do not believe that §409.17 requires an order for outpatient therapy services in a CAH as suggested by the commenters. This regulation requires that a qualified professional pursuant to a plan of care furnish PT, OT, or SLP services, which is not the same as an order. Section 409.17 does not provide for any utilization control or limits on the quantity of outpatient therapy services furnished by CAHs, but rather assures that therapy is furnished under a plan of care by a qualified professional. Further, as explained above, we believe that proper interpretation of the statute requires us to apply the therapy caps and related provisions to therapy services furnished by CAHs. As such, the therapy

caps and related provisions would have a comparable effect on therapy services furnished by a CAH and those furnished by other therapy services providers (unless they are exempted by statute from the application of the caps).

Comment: We received numerous comments stating that our proposal resulted from a misinterpretation of the ATRA, and that it is preferable policy to treat CAHs and hospitals similarly for the purpose of the therapy caps. Several commenters believed that we have misinterpreted the language of the ATRA to conclude that the therapy caps should be applied to services furnished by CAHs. Commenters noted that the ATRA specifies a proxy value to accrue therapy services furnished by CAHs toward the caps, but does not indicate that we should count this value beyond December 31, 2013, or that we should generally subject services furnished by CAHs to the therapy caps. Most of these commenters argued that if Congress had intended to apply the therapy cap to CAHs, it would have explicitly indicated in the ATRA that CAHs should be subject to the therapy caps. One commenter raised concern that "the proposed change is unlawful" since the ATRA neither requires, nor allows the Secretary to revise the federal regulations to permanently subject to the caps outpatient therapy services furnished by CAHs.

Most commenters said that we should treat CAHs and outpatient hospital departments similarly with regard to the therapy caps by continuing to exclude services furnished by CAHs (presumably to the extent such exclusion is required by statute). Commenters argued that a CAH is intended to be "provider of services" by furnishing inpatient and outpatient hospital services in areas where care is severely limited and thereby acts as a "hospital" in the areas that it serves. One commenter believed that our interpretation of the exemption from the therapy caps of outpatient therapy services described under section 1833(a)(8)(B) of the Act and paid under

section 1834(k)(1)(B) of the Act is misguided since the exemption only describes the provider type rather than the provider type and payment methodology for those services. As evidence for this reasoning, the commenter noted that skilled nursing facilities (SNFs), comprehensive outpatient rehabilitation facilities (CORFs), rehabilitation agencies, and home health agencies, described under section 1833(a)(8)(A) of the Act and paid under section 1834(k)(1)(B) of the Act, are not exempt from the therapy caps. The commenter suggested that we make a determination that, based on the statutory definition in section 1861(e) of the Act, a CAH is a hospital in the context of applying the therapy caps, and interpret the hospital services exemption from the therapy caps to include CAHs.

Response: We agree with commenters that the ATRA does not direct or require us to apply the therapy caps to services furnished by CAHs. As noted above, we agree that the ATRA only directed us to count therapy services furnished by CAHs towards the caps. However, the ATRA is not the basis of the proposed change to our regulations. Rather, we based our proposed change on our reassessment of language of section 1833(g) of the Act as added by the BBA.

After considering the comments concerning our interpretation of section 1833(g) of the Act, we again reassessed the statute and reviewed the rationale for our proposal. We continue to conclude that our proposal to revise our regulations to apply the therapy caps to services furnished by CAHs reflects the proper interpretation of section 1833(g) of the statute. We continue to believe that therapy services furnished by a CAH and paid under section 1834(g) of the Act are not described under section 1833(a)(8)(B) of the Act and thus do not meet the requirements of the outpatient hospital exemption. Rather, as we explained in the proposed rule, the outpatient hospital services exemption relates to the specific services described under section 1833(a)(8)(B) of the Act, which delineates both the entities that furnish the services and the

manner in which those services are paid. We acknowledge the commenter's recognition that therapy services furnished by rehabilitation agencies, CORFs, SNFs, and home health agencies (some of which are also considered "providers of services" along with CAHs under section 1861(u) of the statute) are subject to the therapy caps even though they are paid under 1834(k)(1)(B) of the Act, as are hospitals. However, the providers mentioned by the commenters are described under section 1833(a)(8)(A) of the Act rather than section 1833(a)(8)(B) of the Act. The outpatient hospital services exemption only applies to services described under section 1833(a)(8)(B) of the Act. We believe that the statute explicitly exempts only services described under section 1833(a)(8)(B) of the Act, which does not include any services for which payment is not made under section 1834(k)(1)(B) of the Act. We continue to believe that neither services furnished by CAHs, nor those furnished by SNFs, CORFs, rehabilitation agencies, and home health agencies, fall under that exemption. Regardless of whether we consider a CAH as a "hospital" for purposes of the therapy caps, therapy services furnished by CAHs are not described under section 1833(a)(8)(B) of the Act and, as such, do not fall within the scope of the outpatient hospital services exemption from the therapy caps. Therefore, we continue to believe that the outpatient hospital services exemption to the therapy caps under section 1833(g)(1) and (3) of the Act does not apply to outpatient therapy services furnished by a CAH.

<u>Comment</u>: Commenters expressed concern that therapy services furnished by CAHs after January 1, 2014 would be treated differently than therapy services furnished by outpatient hospital departments although both entities are subject to the same regulations regarding outpatient therapy services.

Response: Although we believe it would be preferable policy to treat all outpatient therapy services furnished in all settings consistently, we continue to believe the proper interpretation of the statute requires application of the therapy caps and related policies to services furnished by CAHs. As a result, if the outpatient hospital services exemption is no longer suspended by legislation, there may be differences in the application of the statutory therapy caps and related provisions between outpatient hospitals and CAHs.

After consideration of all comments, we are finalizing our proposal. As proposed, we are including paragraph (e)(1)(iv) under both §410.59 and §410.60 to specify that outpatient occupational therapy, physical therapy and speech-language pathology services furnished by a CAH directly or under arrangements shall be counted towards the annual limitation on incurred expenses as if such services were paid under section 1834(k)(1)(B) of the Act. In order to improve clarity that PT and SLP services are combined for the purposes of applying the cap, but not to change the substance of the current regulations or the proposed changes to the regulations, we are making a modification to the proposal. Specifically, we are adding the phrase "and speech-language pathology" to the text in §410.60(e)(1)(iv). Also as proposed, we are adding new paragraph (e)(2)(v) to §410.59 and (e)(2)(vi) to §410.60. These new paragraphs will expressly include outpatient occupational therapy, physical therapy and speech-language pathology services furnished by a CAH directly or under arrangements in the description of services to which the annual limitation applies. Lastly, as proposed, we are amending the regulation at §410.60(e)(3), which currently excludes services furnished by a CAH from the therapy cap for PT and SLP services, to remove the phrase "or CAH." We received a number of comments that were not related to our proposal to amend our

regulations to specify that the therapy caps and related provisions are applicable to therapy

services furnished by a CAH. These comments pertained to repeal of the therapy caps, the therapy caps exceptions process, the manual medical review process, the therapy MPPR, and Functional Reporting. Because we made no proposals regarding these subjects, these comments are outside of the scope of the proposed rule and, therefore, are not addressed in this final rule with comment period.

J. Requirements for Billing "Incident To" Services

1. Background

Section 1861(s)(2)(A) of the Act establishes the benefit category for services and supplies furnished as incident to the professional services of a physician. The statute specifies that "incident to" services and supplies are "of kinds which are commonly furnished in physicians' offices and are commonly either rendered without charge or included in physicians' bills."

In addition to the requirements of the statute, our regulation at §410.26 sets forth specific requirements that must be met in order for physicians and other practitioners to bill Medicare for incident to physicians' services. Section 410.26(a)(7) limits "incident to" services to those included under section 1861(s)(2)(A) of the Act and that are not covered under another benefit category. Section 410.26(b) specifies (in part) that in order for services and supplies to be paid as "incident to" services under Medicare Part B, the services or supplies must be:

- Furnished in a noninstitutional setting to noninstitutional patients.
- An integral, though incidental, part of the service of a physician (or other practitioner) in the course of diagnosis or treatment of an injury or illness.
- Furnished under direct supervision (as specified under §410.26(a)(2)) of a physician or other practitioner eligible to bill and directly receive Medicare payment.
- Furnished by a physician, a practitioner with an "incident to" benefit, or auxiliary personnel.

In addition to §410.26, there are regulations specific to each type of practitioner who is allowed to bill for "incident to" services. These are found at §410.71(a)(2) (clinical psychologist services), §410.74(b) (physician assistants' services), §410.75(d) (nurse practitioners' services), §410.76(d) (clinical nurse specialists' services), and §410.77(c) (certified nurse-midwives'

services). When referring to practitioners who can bill for services furnished incident to their professional services, we are referring to physicians and these practitioners.

"Incident to" services are treated as if they were furnished by the billing practitioner for purposes of Medicare billing and payment. Consistent with this terminology, in this discussion when referring to the practitioner furnishing the service, we are referring to the practitioner who is billing for the "incident to" service. When we refer to the "auxiliary personnel" or the person who "provides" the service, we are referring to an individual who is personally performing the service or some aspect of it as distinguished from the practitioner who bills for the "incident to" service.

Since we treat "incident to" services as services furnished by the billing practitioner for purposes of Medicare billing and payment, payment is made to the billing practitioner under the PFS, and all relevant Medicare rules apply including, but not limited to, requirements regarding medical necessity, documentation, and billing. Those practitioners who can bill Medicare for "incident to" services are paid at their applicable Medicare payment rate as if they furnished the service. For example, when "incident to" services are billed by a physician, they are paid at 100 percent of the fee schedule amount, and when the services are billed by a nurse practitioner or clinical nurse specialist, they are paid at 85 percent of the fee schedule amount. Payments are subject to the usual deductible and coinsurance amounts.

As the services commonly furnished in physicians' offices and other nonfacility settings have expanded to include more complicated services, the types of services that can be furnished "incident to" physicians' services have also expanded. States have increasingly adopted standards regarding the delivery of health care services in all settings, including physicians' offices, in order to protect the health and safety of their citizens. These state standards often

include qualifications for the individuals who are permitted to furnish specific services or requirements about the circumstances under which services may actually be furnished. For example, since 2009, New York has required that offices in which surgery is furnished must be accredited by a state-approved accredited agency or organization. Similarly, Florida requires certain standards be met when surgery is furnished in offices, including that the surgeon must "examine the patient immediately before the surgery to evaluate the risk of anesthesia and of the surgical procedure to be performed" and "qualified anesthesia personnel shall be present in the room throughout the conduct of all general anesthetics, regional anesthetics and monitored anesthesia care."

Over the past years, several situations have come to our attention where Medicare was billed for "incident to" services that were provided by auxiliary personnel who did not meet the state standards for those services in the state in which the services were furnished. The physician or practitioner billing for the services would have been permitted under state law to personally furnish the services, but the services were provided by auxiliary personnel who were not in compliance with state law in providing the particular service (or aspect of the service).

Practitioners authorized to bill Medicare for services that they furnish to Medicare beneficiaries are required to comply with state law when furnishing services for which Medicare will be billed. For example, section 1861(r) of the Act specifies that an individual can be considered a physician in the performance of any function or action only when legally authorized to practice in the particular field by the state in which he performs such function or action. Section 410.20(b) of our regulations provides that payment is made for services only if furnished by a doctor who is "…legally authorized to practice by the State in which he or she performs the functions or actions, and who is acting within the scope of his or her license." Similar statutory

and regulatory requirements exist for nonphysician practitioners. For example, section 1861(s)(2)(K)(i) of the Act, which provides a benefit category for services of a physician assistant (PA), includes only services that the PA is "...legally authorized to perform by the State in which the services are performed...", and \$410.74(a)(2)(ii) of our regulations provides that the services of a PA are covered only if the PA is "...legally authorized to perform the services in the State in which they are performed..." There are similar statutory and regulatory provisions for nurse practitioner services (1861(s)(2)(K)(ii), \$410.75(b)), certified nurse specialist services (1861(s)(2)(K)(ii), \$410.76(b)), qualified psychologist services (1861(s)(2)(M), \$410.71(a)), and certified nurse-midwife services (1861(s)(2)(L), \$410.77(a)(1)).

However, the Medicare requirements for services and supplies incident to a physician's professional services (§410.26 discussed above), do not specifically make compliance with state law a condition of payment for services (or aspects of services) and supplies furnished and billed as "incident to" services. Nor do any of the regulations regarding services furnished incident to the services of other practitioners contain this requirement. Thus, Medicare has had limited recourse when services furnished incident to a physician's or practitioner's services are not furnished in compliance with state law.

In 2009, the Office of Inspector General issued a report entitled "Prevalence and Qualifications of Nonphysicians Who Performed Medicare Physician Services" (OEI-09-06-00430) that considered in part the qualifications of auxiliary personnel who provided incident to physician services. This report found that services being billed to Medicare were provided by auxiliary personnel. After finding that services were being provided by auxiliary personnel ". . . . who did not possess the required licenses or certifications according to State laws, regulations, and/or Medicare rule" and billed to Medicare the OIG recommended that we revise the "incident

to" rules to, among other things, "...require that physicians who do not personally perform the services they bill to Medicare ensure that no persons except... nonphysicians who have the necessary training, certification, and/or licensure, pursuant to State laws, State regulations, and Medicare regulations personally perform the services under the direct supervision of a licensed physician."

2. Compliance with State Law

To ensure that auxiliary personnel providing services to Medicare beneficiaries incident to the services of other practitioners do so in accordance with the requirements of the state in which the services are furnished and to ensure that Medicare payments can be denied or recovered when such services are not furnished in compliance with the state law, we proposed to add a requirement to the "incident to" regulations at §410.26, Services and supplies incident to a physician's professional services: Conditions. Specifically, we proposed to amend §410.26(b) by redesignating paragraphs (b)(7) and (b)(8) as paragraphs (b)(8) and (b)(9), respectively, and by adding a new paragraph (b)(7) to state that "Services and supplies must be furnished in accordance with applicable State law." We also proposed to amend the definition of auxiliary personnel at §410.26(a)(1) to require that the individual providing "incident to" services "meets any applicable requirements to provide the services, including licensure, imposed by the State in which the services are being furnished."

3. Elimination of Redundant Language

In addition, we proposed to eliminate redundant and potentially incongruent regulatory language by replacing the specific "incident to" requirements currently contained in the regulations relating to each of the various types of practitioners with a reference to the requirements of §410.26. Specifically, we proposed to:

• Revise §410.71(a)(2) regarding clinical psychologists' services to read "Medicare Part B covers services and supplies incident to the services of a clinical psychologist if the requirements of §410.26 are met."

- Revise §410.74(b) regarding physician assistants' services to read "Medicare Part B covers services and supplies incident to the services of a physician assistant if the requirements of §410.26 are met."
- Revise §410.75(d) regarding nurse practitioners' services to read "Medicare Part B
 covers services and supplies incident to the services of a nurse practitioner if the requirements of
 §410.26 are met."
- Revise §410.76(d) regarding certified nurse specialists' services to read "Medicare Part B covers services and supplies incident to the services of a clinical nurse specialist if the requirements of §410.26 are met."
- Revise the language in §410.77(c) regarding certified nurse-midwives' services to read "Medicare Part B covers services and supplies incident to the services of a certified nurse-midwife if the requirements of §410.26 are met."

We noted in the proposed rule that these practitioners are, and would continue to be under this proposal, required to comply with the regulation at \$410.26 for services furnished incident to their professional services. We believe it is redundant and potentially confusing to have separate regulations that generally restate the requirements for "incident to" services of \$410.26 using slightly different terminology. We stated that our goal in proposing the revisions to refer to \$410.26 in the regulation for each practitioner's "incident to" services was to reduce the regulatory burden and make it less difficult for practitioners to determine what is required. Reconciling these regulatory requirements for physicians and all other practitioners who have the

authority to bill Medicare for "incident to" services is also consistent with our general policy to treat nonphysician practitioners similarly to physicians unless there is a compelling reason for disparate treatment. We noted that we believed that this proposal made the requirements clearer for practitioners furnishing "incident to" services without eliminating existing regulatory requirements or imposing new ones and welcomed comments on any requirements that we may have inadvertently overlooked in our proposed revisions, or any benefit that accrues from continuing to carry these separate regulatory requirements.

4. Rural Health Clinics and Federal Qualified Health Centers

The regulations applicable to Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) have similar "incident to" rules, and we proposed to make conforming changes to these regulations. Specifically, we proposed to revise §405.2413(a), which addresses services and supplies incident to physicians' services for RHCs and FQHCs, by redesignating paragraphs (a)(4) and (a)(5) as paragraphs (a)(5) and (a)(6), respectively and by adding a new paragraph (a)(4) that states services and supplies must be furnished in accordance with applicable state law. Additionally, we proposed to amend §405.2415(a), which addresses services incident to nurse practitioner and physician assistant services by redesignating paragraphs (a)(4) and (a)(5) as paragraphs (a)(5) and (a)(6), respectively and by adding a new paragraph (a)(4), which specifies services and supplies must be furnished in accordance with applicable state law. We proposed to amend §405.2452(a), which addresses services and supplies incident to clinical psychologist and clinical social worker services by redesignating paragraphs (a)(4) and (a)(5) as paragraphs (a)(5) and (a)(6), respectively and by adding a new paragraph (a)(4), which states services and supplies must be furnished in accordance applicable

state law. Finally, we also proposed the removal of the word "personal" in §405.2413, §405.2415, and §405.2452 to be consistent with the "incident to" provisions in §410.26.

The following is a summary of the comments we received regarding the proposal to amend our regulations to include the requirement that "incident to" services must be furnished in accordance with applicable state law.

Comment: The vast majority of commenters supported requiring compliance with applicable state law as a condition of payment for "incident to" services. Many of these commenters noted that adoption of this regulation would increase quality of care and safety for Medicare beneficiaries and ensure that funds dedicated to services and supplies are appropriately utilized. We received only two comments opposing the adoption of a condition of payment requiring compliance with state laws. One of these stated that since at least 1997, Medicare has had a "demonstration project" that has tested the effects of lifting state scope of practice restrictions, and that with this proposed regulation we are abruptly ending this demonstration without an assessment of the effects of such action. The other stated that this regulation was unnecessary because section 1156 of the Act requires health care practitioners to ensure that "...the services it furnishes are of a quality that meets professional standards of care...." Some who supported the concept of our proposal suggested that the condition of payment only require compliance with state laws relating to training, certification, and/or licensure. In support of this suggestion, a commenter noted that the broader requirement of compliance with any applicable state laws would allow CMS to deny Medicare payment for technical violations of state laws that are not targeted at patient health or safety, even when care was appropriately delivered and the quality of care not affected. One commenter pointed out that our regulations if revised as proposed would put providers at risk of having to defend False Claims Act actions brought on

the theory that the provider improperly billed for services based on a minor defect with the physician or other practitioner's license or certification; and, in turn that this minor defect is unrelated to the quality of care furnished and outside the scope of practice and should therefore not result in the risk of possible False Claims Act allegations.

Response: After consideration of the comments, we are finalizing our proposal to adopt a new condition of payment imposing a requirement to comply with state laws for services furnished incident to a physician's or other practitioner's professional services. We believe this requirement will protect the health and safety of Medicare beneficiaries and enhance our ability to recover federal dollars when care is not delivered in accordance with state laws. In response to concerns that the proposal should be limited to state laws relating to who could perform the services, such as scope of practice or licensure laws, we believe that there are many and varied state laws that would protect the safety and health of Medicare beneficiaries. As such, we do not believe it would be prudent to limit the applicability as suggested. In response to the commenter's concern regarding technical and unintended violations of state laws, it is important that CMS only pays for services furnished in accordance with state law. In an effort to ensure that services are furnished in accordance with state law, it is expected that practitioners are cognizant of the qualifications of any individuals who provide services incident to the physician (or other practitioner). With regard to the comment stating that this regulation is unnecessary based on section 1156 of the Act, we note that compliance with section 1156 is a condition of eligibility and not an explicit basis for CMS to deny or recover payments for services furnished incident to services of a physician (or other practitioner) where services are not furnished in accordance with state law. After reviewing the comments we conclude that it is beneficial to make explicit as a condition of payment for "incident to" services the requirement to comply with state law. The fact

that another provision of the law might also be relevant to the situation does not mean that both are not appropriate or beneficial to the program. With regard to the comment that we are ending a demonstration project that has existed since at least 1997 without an assessment, we disagree. We are unaware of any such demonstration project either currently underway, or undertaken in the past. Moreover, as we noted in the proposed rule, practitioners furnishing services to Medicare beneficiaries are not exempt from complying with state law.

Comment: Several commenters, including some who supported our proposal, expressed concern about enforcement and expanding the administrative burden on Medicare practitioners. Suggestions were made that we be transparent in implementing the provision and provide ample education on the policy and how it will be enforced. One commenter asked that we "...take into account the already significant administrative burden that physicians face under Medicare, and avoid adding to that burden." Another commenter urged us to work with medical societies, particularly those representing practitioners in rural communities, to ensure the policy is well understood and does not impede beneficiary access to care. It was further suggested that we should know who is actually providing services or at least when services are provided "incident to" the billing professional's services, and that we consider implementing the OIG's recommendation to require the use of modifiers on the claim when reporting "incident to" services.

Response: We do not believe that this condition of payment would increase the administrative burden on practitioners as practitioners are already expected to comply with state law. As we have discussed above, we believe that this provision enhances our ability to deny or recover payments when the condition is not met. With regard to the suggestion that we impose a requirement for practitioners to bill "incident to" services using a modifier, we do not believe

that a modifier requirement would assist in implementing or enforcing this condition of payment. Since a modifier requirement would not assist us in implementing this provision, we are not adopting one at this time. We would also note that there are impediments to imposing a modifier requirement at this time, including that a modifier and required definitions for use of a modifier do not exist. With regard to informing those affected by this change in regulations, we will use our usual methods to alert stakeholders of this new condition of payment and feel confident that the information will be efficiently and effectively disseminated to those who need it.

<u>Comment</u>: One commenter pointed out that states can and do punish individuals for furnishing services inappropriately, and that CMS should therefore leave it to the states to determine whether or when services are provided by an unlicensed professional.

Response: We agree with this commenter that it is primarily the responsibility of states to develop and enforce compliance with licensure laws for health care professionals, and note that nothing in this proposal would impede the states' ability to do so. Nor would anything in this proposal duplicate the states' activities in this arena. Rather, this proposal would reinforce the states' laws by providing explicit authority to limit Medicare payment for "incident to" services to those furnished in accordance with state laws. As noted above, in the absence of our proposed regulation, situations could arise where Medicare would otherwise make payment for services not furnished in accordance with state law. Such situations are not consistent with our recognition of states as principle regulators of health care practices for the protection and benefit of their citizens. The adoption of compliance with state law as a condition of Medicare payment allows us to deny, or if already paid, recover payment when services are not furnished in compliance with state law and thus supports state activities.

<u>Comment</u>: A commenter suggested that we eliminate the new proposed §410.26(b)(7), which requires that "incident to" services be provided in compliance with applicable state law, because it was redundant with §410.26(a)(1).

Response: Section 410.26(a)(1) defines "Auxiliary personnel" whereas §410.26(b)(7) provides the conditions that must be met for Medicare Part B to pay for services and supplies. It is therefore not redundant, but instead necessary, to both define auxiliary personnel and to include the specific requirements that must be met.

In addition to the comments discussed above, we received several comments regarding the "incident to" benefit that were not within the scope of our proposal. Specifically, we received requests to expand the types of practitioners who are allowed to bill Medicare for "incident to" services and to limit auxiliary personnel under our "incident to" regulations to those who cannot bill Medicare directly for their services. Not only are these comments outside the scope of this regulation, but in most respects they are addressed by the Medicare statute and outside our discretion to change.

After consideration of public comments regarding our proposed rule, we are finalizing the changes to our regulations as proposed. The specific regulatory changes being made are described below.

Specifically, we are amending §410.26(a)(7), which defines "auxiliary personnel" to add "and meets any applicable requirements to provide the services, including licensure, imposed by the State in which the services are being furnished." In §410.26(b) we are redesignating paragraphs (b)(7) and (b)(8) as paragraphs (b)(8) and (b)(9), respectively, and adding a new paragraph (b)(7) to state that "Services and supplies must be furnished in accordance with applicable State laws;".

In addition, we are finalizing our proposal to eliminate redundant and potentially incongruent regulatory language by replacing the specific "incident to" requirements currently contained in the regulations relating to each of the various types of practitioners with a reference to the requirements of §410.26. Specifically, we are:

- Revising §410.71(a)(2) regarding clinical psychologist services to read "Medicare Part B covers services and supplies incident to the services of a clinical psychologist if the requirements of §410.26 are met."
- Revising §410.74(b) regarding physician assistants' services to read "Medicare Part B covers services and supplies incident to the services of a physician assistant if the requirements of §410.26 are met."
- Revising §410.75(d) regarding nurse practitioners' services to read "Medicare Part B covers services and supplies incident to the services of a nurse practitioner if the requirements of §410.26 are met."
- Revising §410.76(d) regarding clinical nurse specialists' services to read "Medicare Part B covers services and supplies incident to the services of a clinical nurse specialist if the requirements of §410.26 are met."
- Revising the language in §410.77(c) regarding certified nurse-midwives' services to read "Medicare Part B covers services and supplies incident to the services of a certified nurse-midwife if the requirements of §410.26 are met."

We are also revising the regulations applicable to RHCs and FQHCs to make similar changes. Specifically, we are revising §405.2413(a), which addresses services and supplies incident to physicians' services for RHCs and FQHCs, by redesignating paragraphs (a)(4) and (a)(5) as paragraphs (a)(5) and (a)(6), respectively and by adding a new paragraph (a)(4) that

states "Services and supplies must be furnished in accordance with applicable State laws;". Additionally, we are amending §405.2415(a), which addresses services incident to nurse practitioner and physician assistant services by redesignating paragraphs (a)(4) and (a)(5) as paragraphs (a)(5) and (a)(6), respectively and by adding a new paragraph (a)(4) that "Services and supplies must be furnished in accordance with applicable State laws;". We are amending §405.2452(a), which addresses services and supplies incident to clinical psychologist and clinical social worker services by redesignating paragraphs (a)(4) and (a)(5) as paragraphs (a)(5) and (a)(6), respectively and by adding a new paragraph (a)(4) that states "Services and supplies must be furnished in accordance with applicable State laws."

Finally, we are removing the word "personal" in §405.2413, §405.2415, and §405.2452 to be consistent with the "incident to" provisions in §410.26 Services and supplies incident to a physician's professional services: Conditions.

The changes being adopted in this final rule with comment period are consistent with the traditional approach of relying primarily on the states to regulate the health and safety of their residents in the delivery of health care services. Throughout the Medicare program, and as evidenced by several examples above, the qualifications required for the delivery of health care services are generally determined with reference to state law. As discussed above, our current regulations governing practitioners billing Medicare for services personally furnished include a basic requirement to comply with state law when furnishing Medicare covered services.

However, the Medicare regulations for "incident to" services and supplies did not specifically make compliance with state law a condition of payment for services and supplies furnished and billed as incident to a practitioner's services. In addition to health and safety benefits that we believe will accrue to Medicare beneficiaries, these changes will help to assure that federal

dollars are not expended for services that do not meet the standards of the states in which they are being furnished while providing the ability for the federal government to recover funds paid where services and supplies are not furnished in accordance with these requirements.

K. Chronic Care Management (CCM) Services

As we discussed in the CY 2013 PFS final rule with comment period, we are committed to supporting primary care and we have increasingly recognized care management as one of the critical components of primary care that contributes to better health for individuals and reduced expenditure growth (77 FR 68978). Accordingly, we have prioritized the development and implementation of a series of initiatives designed to improve payment for, and encourage long-term investment in, care management services. These initiatives include the following programs and demonstrations:

- The Medicare Shared Savings Program (described in "Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations; Final Rule" which appeared in the November 2, 2011
 Federal Register (76 FR 67802)).
- The testing of the Pioneer ACO model, designed for experienced health care organizations (described on the Center for Medicare and Medicaid Innovation's (Innovation Center's) website at innovations.cms.gov/initiatives/ACO/Pioneer/index.html).
- The testing of the Advance Payment ACO model, designed to support organizations participating in the Medicare Shared Savings Program (described on the Innovation Center's website at innovations.cms.gov/initiatives/ACO/Advance-Payment/index.html).
- The Primary Care Incentive Payment (PCIP) Program (described on the CMS website at <u>www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/PCIP-2011-Payments.pdf</u>).
- The patient-centered medical home model in the Multi-payer Advanced Primary Care Practice (MAPCP) Demonstration designed to test whether the quality and coordination of health care services are improved by making advanced primary care practices more broadly available (described on the CMS website at www.cms.gov/Medicare/Demonstration-

Projects/DemoProjectsEvalRpts/downloads/mapcpdemo Factsheet.pdf).

• The Federally Qualified Health Center (FQHC) Advanced Primary Care Practice demonstration (described on the CMS website at www.cms.gov/Medicare/Demonstration-

<u>Projects/DemoProjectsEvalRpts/downloads/mapcpdemo_Factsheet.pdf</u> and the Innovation Center's website at <u>innovations.cms.gov/initiatives/FQHCs/index.html</u>).

• The Comprehensive Primary Care (CPC) initiative (described on the Innovation Center's website at innovations.cms.gov/initiatives/Comprehensive-Primary-Care-Initiative/index.html). The CPC initiative is a multi-payer initiative fostering collaboration between public and private health care payers to strengthen primary care in certain markets across the country.

In addition, HHS leads a broad initiative focused on optimizing health and quality of life for individuals with multiple chronic conditions. HHS' Strategic Framework on Multiple Chronic Conditions outlines specific objectives and strategies for HHS and private sector partners centered on strengthening the health care and public health systems; empowering the individual to use self-care management; equipping care providers with tools, information, and other interventions; and supporting targeted research about individuals with multiple chronic conditions and effective interventions. Further information on this initiative can be found on the HHS website at http://www.hhs.gov/ash/initiatives/mcc/index.html.

In coordination with all of these initiatives, we also have continued to explore potential refinements to the PFS that would appropriately value care management within Medicare's statutory structure for fee-for-service physician payment and quality reporting. For example, in the CY 2013 PFS final rule with comment period, we adopted a policy to pay separately for care management involving the transition of a beneficiary from care furnished by a treating physician during a hospital stay to care furnished by the beneficiary's primary physician in the community (77 FR 68978 through 68993). We view potential refinements to the PFS such as these as part of a broader strategy that relies on input and information gathered from the initiatives described above, research and demonstrations from other public and private stakeholders, the work of all parties involved in the potentially misvalued code initiative, and from the public at large.

1. Patient Eligibility for Separately Payable Non-Face-to-Face Chronic Care Management Services

Under current PFS policy, the payment for non-face-to-face care management services is bundled into the payment for face-to-face E/M visits because care management is a component of those E/M services. The pre- and post-encounter non-face-to-face care management work is included in calculating the total work for the typical E/M services, and the total work for the typical service is used to develop RVUs for the E/M services. In the CY 2012 PFS proposed rule, we highlighted some of the E/M services that include substantial care management work. Specifically, we noted that the vignettes that describe a typical service for mid-level office/outpatient services (CPT codes 99203 and 99213) include furnishing care management, communication, and other necessary care management related to the office visit in the post-service work (76 FR 42917).

However, the physician community continues to tell us that the care management included in many of the E/M services, such as office visits, does not adequately describe the typical non-face-to-face care management work involved for certain categories of beneficiaries. In addition, there has been substantial growth in medical practices that are organized as medical homes and devote significant resources to care management as one of the keys to improve the quality and coordination of health care services. Practitioners in these medical homes have also indicated that the care management included in many of the E/M services does not adequately describe the typical non-face-to-face care management work that they furnish to patients.

Because the current E/M office/outpatient visit CPT codes were designed to support all office visits and reflect an overall orientation toward episodic treatment, we agree that these E/M codes may not reflect all the services and resources required to furnish comprehensive, coordinated care management for certain categories of beneficiaries. For example, we currently pay physicians separately for the non face-to-face care plan oversight services furnished to beneficiaries under the care of home health agencies or hospices and we currently pay separately for care management services furnished to beneficiaries transitioning from care furnished by a treating physician during a hospital stay to care furnished by the beneficiary's primary physician in the community.

Similar to these situations, we believe that the resources required to furnish chronic care management services to beneficiaries with multiple (that is, two or more) chronic conditions are not adequately reflected in the existing E/M codes. Therefore, for CY 2015, we proposed to establish a separate payment under the PFS for chronic care management services furnished to patients with multiple chronic conditions that are expected to last at least 12 months or until the death of the patient, and that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline.

We also stated our intent to develop standards for furnishing chronic care management services to ensure that the physicians and practitioners who bill for these services have the capability to provide them.

<u>Comment</u>: The vast majority of commenters overwhelmingly supported the broad policy of paying separately for non-face-to-face chronic care management services, but submitted comments on many specific aspects of our proposal.

Response: We appreciate the widespread support expressed by commenters for our proposed policy. We address the more specific comments below in this section.

<u>Comment</u>: Some commenters supported our proposed patient eligibility for chronic care management services, at least for the initial implementation of separate payment for the services. Typical of these comments was this statement by one commenter:

"CMS should initially offer these services to patients with multiple chronic conditions that are expected to last at least 12 months or until the death of the patient, and that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline."

We also received comments indicating that the patient eligibility should be broadened, for example, to allow eligibility for patients with one condition or for all patients in a practice that meets the practice standards we establish.

On the other hand, some commenters believed that the eligible patient population should be narrowed. Many of these commenters indicated that the benefits of chronic care management are likely to increase with thethe patient's acuity and risk. Many commenters indicated that the criteria described in

the prefatory language for the complex chronic care coordination CPT codes 99487-99489 describes a narrower and more appropriate patient population. The CPT criteria for CY 2014 currently state:

"Patients who require complex chronic care coordination services may be identified by practicespecific or other published algorithms that recognize multiple illnesses, multiple medication use, inability to perform activities of daily living, requirement for a caregiver, and/or repeat admissions or emergency department visits. Typical adult patients take or receive three or more prescription medications and may also be receiving other types of therapeutic interventions (eg, physical therapy, occupational therapy) and have two or more chronic continuous or episodic health conditions expected to last at least 12 months, or until the death of the patient, that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline. Typical pediatric patients receive three or more therapeutic interventions (eg, medications, nutritional support, respiratory therapy) and have two or more chronic continuous or episodic health conditions expected to last at least 12 months, or until the death of the patient, that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline. Because of the complex nature of their diseases and morbidities, these patients commonly require the coordination of a number of specialties and services. In some cases, due to inability to perform IADL/ADL and/or cognitive impairment the patient is unable to adhere to the treatment plan without substantial assistance from a caregiver. For example, patients may have medical and psychiatric behavioral co-morbidities (eg, dementia and chronic obstructive pulmonary disease or substance abuse and diabetes) that complicate their care. Social support requirements or access to care difficulties may cause a need for these services. Medical, functional, and/or psychosocial problems that require medical decision making of moderate or high complexity and extensive clinical staff support are required."

MedPAC and other some commenters did not recommend specific alternative patient eligibility criteria, but stated that CMS should develop such criteria to better target the beneficiaries requiring significant management. One commenter recommended that the eligible patient population be narrowed to patients with four or more chronic conditions.

Response: As we stated in the proposed rule, we believe that the resources required to furnish chronic care management services to beneficiaries with two or more chronic conditions are not adequately reflected in the existing E/M codes. Furnishing care management to beneficiaries with multiple chronic conditions requires multidisciplinary care modalities that involve: regular physician development and/or revision of care plans; subsequent reports of patient status; review of laboratory and other studies; communication with other health professionals not employed in the same practice who are involved in the patient's care; integration of new information into the care plan; and/or adjustment of medical therapy.

Our proposal was also supported by an analysis of Medicare claims for patients with selected multiple chronic conditions (see http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Chronic-Conditions/Downloads/2012Chartbook.pdf). This analysis indicated that patients with these selected multiple chronic conditions are at increased risk for hospitalizations, use of post-acute care services, and emergency department visits. We continue to believe these findings would hold in general for patients with multiple chronic conditions that are expected to last at least 12 months or until the death of the patient, and that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline. (We note that we did not propose to limit the eligible chronic conditions to those contained in our Medicare data analysis.) We continue to believe that successful efforts to improve chronic care management for these patients could improve the quality of care while simultaneously decreasing costs (for example, through reductions in hospitalizations, use of post-acute care services, and emergency department visits.) Therefore, we agree with the commenters who supported our proposed patient eligibility criteria.

While we also agree with the commenters who stated that the benefits from chronic care management are likely to increase the greater the acuity and risk to the patient, we disagree that the benefits and higher resource requirements for furnishing the service are limited to those even higher risk patients within the population of patients with two or more chronic conditions. Therefore, we disagree that the eligible patient population should be narrowed.

We also disagree with commenters who indicated that we should immediately expand the eligible patient population, for example, to include some patients with a single chronic condition or all the patients in a practice that meets future standards. It is not clear at this time that the resources required to provide typical chronic care management to these patients are not reflected adequately in the existing E/M codes. However, as we indicated in the proposed rule, we have over time recognized certain categories of beneficiaries for whom we allow separate payment for care management. We have not indicated that we have exhaustively identified all such categories of beneficiaries. We will continue to carefully consider whether there are categories of patients for whom the resources required to provide chronic care

management services are not adequately reflected in the existing E/M codes. We may consider changes to the patient eligibility in future rulemaking.

In summary, we are finalizing without modification our proposed patient eligibility for chronic care management services to be patients with multiple chronic conditions that are expected to last at least 12 months or until the death of the patient, and that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline.

We note that although we are finalizing our proposed eligibility criteria, since we agree with commenters that the benefits from chronic care management are likely to increase with the greater the acuity and risk to the patient, we expect that physicians and other practitioners will particularly focus on higher acuity and higher risk patients (for example, patients with four or more chronic conditions as suggested by one commenter) when furnishing chronic care management services to eligible patients.

<u>Comment</u>: Many commenters found our use of the term "complex" to describe these services to be confusing in light of the number of Medicare beneficiaries within a practice potentially meeting our proposed eligibility criteria, and suggested that the word could be interpreted to significantly narrow the appropriate patient population eligible for chronic care management services.

Response: We regret any confusion generated by our proposed use of the term "complex" to describe the chronic care management services that are not adequately reflected in the existing E/M codes. Although the provision of these services is complex relative to the care management reflected in the existing E/M codes, we understand the confusion on the part of commenters regarding the number of patients within a practice that are potentially eligible for the service versus those that would be considered "complex." Therefore, to reduce potential confusion, we will revise the code description for these services to describe "chronic care management" services rather than complex chronic care management services. We note that we have revised references throughout this preamble to remove the word "complex" from the description of these services.

2. Scope of Chronic Care Management Services

We proposed that the scope of chronic care management services includes:

• The provision of 24-hour- a-day, 7-day- a-week access to address a patient's acute chronic care needs. To accomplish these tasks, we would expect that the patient would be provided with a means to make timely contact with health care providers in the practice to address urgent chronic care needs regardless of the time of day or day of the week. Members of the chronic care team who are involved in the after-hours care of a patient must have access to the patient's full electronic medical record even when the office is closed so they can continue to participate in care decisions with the patient.

- Continuity of care with a designated practitioner or member of the care team with whom the patient is able to get successive routine appointments.
- Care management for chronic conditions including systematic assessment of patient's medical, functional, and psychosocial needs; system-based approaches to ensure timely receipt of all recommended preventive care services; medication reconciliation with review of adherence and potential interactions; and oversight of patient self-management of medications. In consultation with the patient and other key practitioners treating the patient, the practitioner furnishing chronic care management services should create a patient-centered plan of care document to assure that care is provided in a way that is congruent with patient choices and values. A plan of care is based on a physical, mental, cognitive, psychosocial, functional and environmental (re) assessment and an inventory of resources and supports. It is a comprehensive plan of care for all health issues. It typically includes, but is not limited to, the following elements: problem list, expected outcome and prognosis, measurable treatment goals, symptom management, planned interventions, medication management, community/social services ordered, how the services of agencies and specialists unconnected to the practice will be directed/coordinated, identify the individuals responsible for each intervention, requirements for periodic review and, when applicable, revision, of the care plan. The provider should seek to reflect a full list of problems, medications and medication allergies in the electronic health record to inform the care plan, care coordination and ongoing clinical care.
- Management of care transitions within health care including referrals to other clinicians, visits following a patient visit to an emergency department, and visits following discharges from hospitals and

skilled nursing facilities. The practice must be able to facilitate communication of relevant patient information through electronic exchange of a summary care record with other health care providers regarding these transitions. The practice must also have qualified personnel who are available to deliver transitional care services to a patient in a timely way so as to reduce the need for repeat visits to emergency departments and re-admissions to hospitals and skilled nursing facilities.

- Coordination with home and community based clinical service providers required to support a patient's psychosocial needs and functional deficits. Communication to and from home and community based providers regarding these clinical patient needs must be documented in practice's medical record system.
- Enhanced opportunities for a patient to communicate with the provider regarding their care through not only the telephone but also through the use of secure messaging, internet or other asynchronous non face-to-face consultation methods.

<u>Comment</u>: Some commenters supported our proposed scope of services, indicating that the requirements are consistent with what is expected in a primary care medical home. Other commenters, while generally supportive of the proposed scope of services, provided comments on specific aspects of the proposed scope.

Response: We agree with the commenters who supported our proposed scope of services and agree that the requirements are consistent with what is expected in a primary care medical home. We summarize and respond to comments on specific aspects of the proposed scope below.

Comment: Some commenters indicated that while they agreed with the goal of having members of the chronic care team who are involved in the after-hours care of a patient having access to the patient's full EHR, that this was not currently possible for too many physicians who would otherwise be able to provide this service. Some commenters indicated that many practices will be using EHR systems that qualify for Meaningful Use Stage 2, but that do not support 24/7 remote access. Some commenters suggested that the 24/7 EHR access requirement be changed to require that members of the chronic care team have access to timely EHR information (that is, through the EHR or other formats.)

Response: Given that the comments on our proposed policy to require 24/7 access to the EHR were generally part of broader comments on the role of EHRs in the standards that must be met in order to furnish chronic care management services, we intend to address this issue in future rulemaking to establish the standards. Summaries of these broader comments can be found below in the standards section.

<u>Comment</u>: Some commenters stated that it was not feasible in many practices for a patient's personal practitioner or another clinical team member to be available on a 24/7 basis for every patient. Other commenters recommended gradually phasing in this requirement over time.

Response: The evolving medical literature on chronic care management and patient centered medical homes emphasizes the central importance of members of the care team being available 24/7 to address a patient's acute chronic care needs. Moreover, we believe the 24/7 availability of the care team is an important factor contributing to higher resource costs for these services that are not currently reflected in E/M services. Therefore, we disagree with commenters who requested that we relax or phase in the 24/7 requirement.

<u>Comment</u>: Some commenters requested that we clarify the scope of services with respect to caregivers for patients with chronic care needs. Some of these commenters recommended that we require providers to address the needs of caregivers, especially caregivers who are Medicare beneficiaries, since caregivers are at elevated risk of health issues from emotional and physical stresses.

Response: As with transitional care management (77 FR 68989), communication that is within the scope of services for chronic care management includes communication with the patient and caregiver. We also agree with commenters that caregivers who are Medicare beneficiaries, as with any Medicare beneficiary, should be provided with needed high quality, efficient care congruent with the patient's choices and values. We note, however, that we do not have the statutory authority to extend Medicare benefits to individuals who are not eligible for those benefits.

<u>Comment</u>: While the majority of commenters expressed support for our proposal to require a patient-centered plan of care, some commenters believed that this requirement was not necessary in all

cases. These commenters suggested that the requirement be changed to require a plan of care document as needed.

Response: We disagree with these comments. As we indicated in the propose rule, we believe that patients with multiple chronic conditions are at increased risk for hospitalizations, use of post-acute care services, and emergency department visits. Given this increased risk, we believe that a patient-centered plan of care document is a critical tool to help ensure appropriate care management for these patients. In the absence of such of document, we believe there would be significantly greater potential for gaps in care coordination. In addition, we received many comments supporting active involvement of the patient and caregiver in chronic care management. We believe our requirement that a written or electronic copy of the patient-centered plan of care document be provided to the patient facilitates this involvement.

<u>Comment</u>: Some commenters expressed concern regarding our proposal to include enhanced opportunities for a patient to communicate with the provider regarding their care through not only the telephone but also through the use of secure messaging, internet or other asynchronous non face-to-face consultation methods. They indicated that many patients and/or caregivers may not be capable of using this type of communication, even if the practice is equipped to provide it.

Response: We disagree with these comments. Recognizing the growing use of, and patient and caregiver interest in, asynchronous communication through secure email, text and other modalities to support access to health care, we believe that it is reasonable for beneficiaries and their caregivers who would receive non-face-to-face chronic care management services to be able to communicate with the practice not only by telephone but through asynchronous communication modalities. We note that although the expectation is for the practice to provide these communication options, there is no requirement that the practice ensure that every patient and caregiver makes use of these options.

<u>Comment</u>: Some commenters requested that we explicitly require the chronic care management practitioner to consider various specific services or disease specific services when furnishing the scope of chronic care management services.

Response: In our proposed scope of services, we stated that, "A plan of care is based on a physical, mental, cognitive, psychosocial, functional and environmental (re)assessment and an inventory of resources and supports. It is a comprehensive plan of care for all health issues (emphasis added)." Since the plan of care, as we described it, is to be comprehensive, we do not believe it is necessary for the scope of services to exhaustively list specific possible services that the chronic care management practitioner should consider when furnishing the scope of chronic care management services.

In summary, we are finalizing the following as the scope of chronic care management services.

- The provision of 24-hour- a-day, 7-day- a-week access to address a patient's acute chronic care needs. To accomplish these tasks, we would expect that the patient and caregiver would be provided with a means to make timely contact with health care providers in the practice to address the patient's urgent chronic care needs regardless of the time of day or day of the week.
- Continuity of care with a designated practitioner or member of the care team with whom the patient is able to get successive routine appointments.
- Care management for chronic conditions including systematic assessment of patient's medical, functional, and psychosocial needs; system-based approaches to ensure timely receipt of all recommended preventive care services; medication reconciliation with review of adherence and potential interactions; and oversight of patient self-management of medications. In consultation with the patient, caregiver, and other key practitioners treating the patient, the practitioner furnishing chronic care management services should create a patient-centered plan of care document to assure that care is provided in a way that is congruent with patient choices and values. A plan of care is based on a physical, mental, cognitive, psychosocial, functional and environmental (re)assessment and an inventory of resources and supports. It is a comprehensive plan of care for all health issues. It typically includes, but is not limited to, the following elements: problem list, expected outcome and prognosis, measurable treatment goals, symptom management, planned interventions, medication management, community/social services ordered, how the services of agencies and specialists unconnected to the practice will be directed/coordinated, identify the individuals responsible for each intervention, requirements for periodic review and, when applicable,

revision, of the care plan. The provider should seek to reflect a full list of problems, medications and medication allergies in the electronic health record to inform the care plan, care coordination and ongoing clinical care.

- Management of care transitions within health care including referrals to other clinicians, visits following a patient visit to an emergency department, and visits following discharges from hospitals and skilled nursing facilities. The practice must be able to facilitate communication of relevant patient information through electronic exchange of a summary care record with other health care providers regarding these transitions. The practice must also have qualified personnel who are available to deliver transitional care services to a patient in a timely way so as to reduce the need for repeat visits to emergency departments and re-admissions to hospitals and skilled nursing facilities.
- Coordination with home and community based clinical service providers required to support a patient's psychosocial needs and functional deficits. Communication to and from home and community based providers regarding these clinical patient needs must be documented in practice's medical record system.
- Enhanced opportunities for a patient and caregiver to communicate with the provider regarding the patient's care through not only the telephone but also through the use of secure messaging, internet or other asynchronous non face-to-face consultation methods.

We also note that we continue to assess the potential impact of the scope of our chronic care management policy on our current programs and demonstrations designed to improve payment for, and encourage long-term investment in, care management services. Likewise, to assure that there are not duplicate payments for delivery of care management services, we continue to consider whether such payments are appropriate for providers participating in other programs and demonstrations.

3. Standards for Furnishing Chronic Care Management Services

Not all physicians and nonphysician practitioners who wish to furnish chronic care management services currently have the capability to fully furnish the scope of these services without making additional investments in technology, staff training, and the development and maintenance of systems and

processes to furnish the services. We stated in the proposed rule that we intended to establish standards that would be necessary to furnish high quality, comprehensive and safe chronic care management services. We also stated that one of the primary reasons for our 2015 implementation date was to provide sufficient time to develop and obtain public input on the standards. Since we continue to believe that practice standards are one of the most critical components of our chronic care management policy. We are developing the standards in 2014 and will implement them in 2015. They will be established through notice and comment rulemaking for CY 2015 PFS.

In the proposed rule (78 FR 43338-43339), we solicited public comments for suggestions regarding standards for furnishing chronic care management. Although we solicited comments, we did not propose to adopt any specific standards and are, therefore, not finalizing a policy relating to this issue in this final rule with comment period.

Below are our responses to public comments received. As stated above, the public comments received for these potential standards for chronic care management are beyond the scope of the proposed rule, and therefore, the adoption of any such standards would be addressed through separate notice-and-comment rulemaking.

<u>Comment:</u> Some commenters were in favor of establishing standards for furnishing chronic care management services, generally supporting CMS's acknowledgement of the critical importance of managing care for these Medicare beneficiaries with chronic conditions. Commenters also believe that care coordination is an integral part of improving patient care.

Many commenters expressed concerns and did not support establishing standards for furnishing chronic care management services as we discussed in the proposed rule (78 FR 43338-43339). Some commenters stated the standards we suggested were too aggressive, needed clarification and/or refinement, and were overly burdensome citing that adoption should be delayed, perhaps for years or indefinitely. Commenters suggested that practice capabilities as outlined could exclude many physicians from furnishing these services, despite the physicians being specially trained in chronic care management and having demonstrated the ability to furnish significant quality of care. Many commenters suggested

that CMS partner (through an advisory group, workgroups, etc.) with interested stakeholders, obtain public input, and work with the CMS Innovation Center to continue developing and refining more reasonable potential future standards for furnishing chronic care management in order to ensure that the physicians who bill for these services have the capabilities to furnish them. Some commenters suggested integration of chronic care management standards with the State laws governing the practice of medicine. Commenters also urged CMS not to impose requirements that would preclude specialists from furnishing these critical services.

Response: We appreciate commenters' suggestions and will consider these comments for any future rulemaking on this topic.

As discussed in the proposed rule, potential standards (78 FR 43338-43339) could include the following:

• The practice must be using a certified Electronic Health Record (EHR) for beneficiary care that meets the most recent HHS regulatory standard for meaningful use. The EHR must be integrated into the practice to support access to care, care coordination, care management, and communication.

Comment: Commenters generally supported the value of EHRs in regard to the capabilities to enhance the quality of care for chronic care management. Commenters requested that CMS clarify the following issues if CMS were to move forward with meaningful use as a standard for chronic care management: how a provider new to Medicare or new to a practice would be treated, and how a provider would be treated who formerly met meaningful use but failed to do so in a subsequent year (specifically, whether the practice would be required to repay the chronic care management payment, and whether the practice would have to stop providing these services to beneficiaries in the future). Other commenters noted that while EHRs may facilitate documentation, they are being replaced by "cloud-based" data repositories for beneficiary medical records and social media is being used for communication solutions.

Many commenters did not support requiring the practice to use a certified EHR, some questioning whether an EHR is really essential to providing these services. These commenters discouraged CMS from including meaningful use as a standard for chronic care management, noting that it is premature to

link these services to meaningful use, and that requiring meaningful use as a standard should be delayed until the meaningful use policy has been stabilized and more practices have achieved it. Commenters generally expressed concern regarding linking the provision of chronic care management to meaningful use as practices would have to delay furnishing care management for a full year until they have met meaningful use, denving their patients the benefit of those services. Commenters urged CMS not to require a specific stage of meaningful use certification. Commenters urged elimination of this requirement noting it interfered with the physician's prerogatives and practice; and suggesting that it has nothing to do with how effectively a physician manages patients with chronic conditions. Some commenters suggested that the notion that there should be immediate online access to every patient's complete EHR is unrealistic for many practices (that is, internet access issues, 24/7 availability of the full EHR, on-call health professional being from a different practice and not having access, etc.), particularly those who would most benefit from the potential chronic care management reimbursement. Commenters also noted EHR interoperability is not yet attainable by the vast majority of physicians across the country. Many commenters suggested CMS consider flexibility (that is, a phased-in approach) in requiring EHRs to avoid excluding otherwise qualified practices in areas of need. Some commenters noted that phasing in EHR requirements would aid those smaller practices, or rural areas, that do not currently utilize EHRs and thus would not be able to be reimbursed for furnishing beneficiaries with chronic care management services. Other commenters expressed concern that this requirement could pose a problem for small practices (that is, economically depressed, medically underserved, etc.) for which the expense of obtaining and implementing EHR systems could be prohibitive despite the fact they could meet the remainder of the requirements for chronic care management. Commenters raised concerns that language in the preamble suggests that all practitioners participating in the care of a beneficiary receiving chronic care management services would need to be able to share information related to the care plan electronically, and that it would be very difficult to meet this requirement as not all practices have access to electronic means of communication.

Response: We appreciate commenters' suggestions and will consider these comments for any future rulemaking on this topic.

• The practice must employ one or more advanced practice registered nurses or physicians assistants whose written job descriptions indicate that their job roles include and are appropriately scaled to meet the needs for beneficiaries receiving services in the practice who require chronic care management services furnished by the practice.

Comment: Some commenters supported the requirement to employ non-physician professionals, and encouraged CMS to expand this list to include registered nurses, pharmacists (particularly hematology/oncology clinical specialist pharmacists), social workers, Emergency Department physicians, "caregivers" (that is, those that help with Alzheimer's disease and dementia patients), "direct-care worker," and other specialists such as hematologists, cardiologists, and nephrologists. Some commenters sought clarification regarding whether advanced practice nurse practitioners and physician assistants would have to be available 24/7, and what type of chronic care management services they must furnish.

Many commenters, however, were not in support of the requirement that advanced practice nurses or physician assistants must be employed by the medical practice. Commenters urged elimination of this requirement noting that it interfered with the physician's prerogatives; indicating that this staffing requirement would have little, if anything, to do with how effectively a physician manages patients with chronic conditions, and suggesting that it could be considered cost prohibitive. Some commenters urged CMS to relax this requirement and recognize that these services could be effectively performed by appropriately trained, licensed, and, when applicable, credentialed clinical staff. Commenters recommended that CMS not prescribe the hiring decisions for practices to be eligible to furnish chronic care management services. Commenters suggested that the agency instead should provide greater flexibility for practices to demonstrate that they have the structural capabilities, personnel, and systems to coordinate care effectively, through their own engagement with patients, as well as by having other qualified health care professionals available, either within the practice itself or through external arrangements to furnish chronic care management services.

Some commenters suggested that, under certain circumstances independently contracted (but not necessarily employed) personnel could participate in furnishing these services under the general supervision of a physician or non-physician practitioner, and sought clarification on whether "employ" could include "contract" personnel. Other commenters requested that the standards recognize that nurses can perform this work under the direction and supervision of physicians, especially since many practices employ registered nurses who are well qualified to provide care coordination. Some commenters believed that this requirement was particularly ill-advised and inappropriate, and strongly disagreed that employment of this level of staff should be a consideration in furnishing these services. Other commenters noted that this requirement would deter small and rural practices from offering chronic care management services. Commenters supported care teams/team-based care, but indicated that a practice should have the discretion to hire and develop those care teams, and not be required specifically to hire advanced practice nurse practitioners or physician assistants. Some commenters suggested that a "care manager" concept could be used, which could be a registered nurse, social worker, advanced practice nurse or physician assistant who has received training to perform the service. Commenters also suggested that CMS revise the requirement regarding who must employ the care manager to also allow the practice, or physician organization on the practice's behalf, to be the employer.

Response: We appreciate commenters' suggestions and will consider these comments for any future rulemaking on this topic.

• The practice must be able to demonstrate the use of written protocols by staff participating in the furnishing of services that describe: (1) the methods and expected "norms" for furnishing each component of chronic care management services furnished by the practice; (2) the strategies for systematically furnishing health risk assessments to identify all beneficiaries eligible and who may be willing to participate in the chronic care management services; (3) the procedures for informing eligible beneficiaries about chronic care management services and obtaining their consent; (4) the steps for monitoring the medical, functional and social needs of all beneficiaries receiving chronic care management services; (5) system based approaches to ensure timely furnishing of all recommended

preventive care services to beneficiaries; (6) guidelines for communicating common and anticipated clinical and non-clinical issues to beneficiaries; (7) care plans for beneficiaries post-discharge from an emergency department or other institutional health care setting, to assist beneficiaries with follow up visits with clinical and other suppliers or providers, and in managing any changes in their medications; (8) a systematic approach to communicate and electronically exchange clinical information with and coordinate care among all service providers involved in the ongoing care of a beneficiary receiving chronic care management services; (9) a systematic approach for linking the practice and a beneficiary receiving chronic care management services with long-term services and supports including home and community-based services; (10) a systematic approach to the care management of vulnerable beneficiary populations such as racial and ethnic minorities and people with disabilities; and (11) patient education to assist the beneficiary to self-manage a chronic condition that is considered at least one of his/her chronic conditions. These protocols must be reviewed and updated as is appropriate based on the best available clinical information at least annually.

Comment: Some commenters expressed support for the outlined written protocols. A few commenters suggested that CMS develop educational materials to be made available to patients so they better understand these services. Commenters suggested the 11th written protocol be revised (to be more interactive) to read "provide written protocols that describe collaborative problem solving/decision making that supports the patient in self-managing their chronic health conditions." Other commenters believe that physicians and other providers who care for chronically ill patients can be better supported with evidence-based guidelines, specialty expertise, and information systems; such as, providers encouraging patients (through partnerships with community organizations, etc.) to participate in medical systems like peer support groups, exercise programs, nurse educators, or dieticians.

Commenters urged CMS to revise this requirement to provide more flexibility for practices to demonstrate they have their own protocols to ensure that patients with chronic diseases have timely access to physicians and other team members within a realistic timeframe (that is, practices could be required to demonstrate that their patients have access the same or next day by phone, email,

telemedicine, or in person). Other commenters suggested CMS give more consideration to therapy services, medication management, discharge planning, care coordination, and caregiver education. Commenters also asked CMS to clarify that the practice reporting these chronic care management services does not have to perform all care management itself, and that other practices or healthcare professionals can perform some services in coordination with the reporting practice. Commenters conveyed individuals with Alzheimer's and dementias may not be able to participate in the development of a care plan in the same capacity as individuals who are not cognitively impaired. Some commenters requested CMS go a step further in noting the importance of coordination with direct-care workers and family caregivers, and requiring that this communication be documented as well.

Response: We appreciate commenters' suggestions and will consider these comments for any future rulemaking on this topic.

• All practitioners, including advanced practice registered nurses or physicians assistants, involved in the furnishing of chronic care management services must have access at the time of service to the beneficiary's EHR that includes all of the elements necessary to meet the most recent HHS regulatory standard for meaningful use. This includes any and all clinical staff furnishing after hours care to ensure that the chronic care management services are available with this level of EHR support in the practice or remotely through a Virtual Private Network (VPN), a secure website, or a health information exchange (HIE) 24 hours per day and 7 days a week.

Comment: Commenters were generally in support of the concept that 24/7 access to the beneficiary's EHR would be a tremendous enhancement to furnishing chronic care management. Some commenters noted that many physicians practice in more than one setting, which can make it more challenging for them to furnish all beneficiaries with 24/7 EHR support to providers and care staff. Commenters noted that many of their members do not have the resources to evaluate patients 24/7; therefore, commenters urged CMS to clarify the 24/7 support can be furnished by members of the chronic care team by phone, or allow more flexibility in this requirement until the agency can assess the impact it may have on beneficiary access to chronic care management services. Some commenters noted that many

physicians can access their own organization's EHR both in and outside typical business hours, but do not currently have "real-time" access to all of the EHR data for beneficiaries under their care, especially if they are moving provider settings.

Response: We appreciate commenters' suggestions and will consider these suggestions for any future rulemaking.

Some have suggested that, to furnish these services, practices could be recognized as a medical home by one of the national organizations (including the National Committee for Quality Assurance (NCQA), the Accreditation Association for Ambulatory Health Care, The Joint Commission, URAC, etc.), which are formally recognizing primary care practices as a patient-centered medical home. We understand there are differences among the approaches taken by national organizations that formally recognize medical homes and therefore, we solicited comment on these and other potential care coordination standards, and the potential for CMS recognizing a formal patient-centered medical home designation as one means for a practice to demonstrate it has met any final care coordination standards for furnishing chronic care management services.

Comment: Some commenters supported recognizing a patient centered medical home model to meet the care coordination standards. Commenters recommended that CMS allow for multiple pathways for accreditation recognition, and/or certification of patient centered medical homes and patient centered medical home neighborhood practices, noting other entities offer these programs, such as URAC and The Joint Commission. Some commenters supported the specialty practice recognition program, under NCQA, to be included to enable specialists to be able to participate. Commenters also suggested that CMS include other approaches to recognize medical homes as developed by private health plans and within CMS via its Innovation Center Comprehensive Primary Care Initiative, some of which may not have been formally certified by an accreditation entity. Commenters noted medical homes would be good candidates to provide chronic care management, but Patient Centered Medical Homes represent a relatively small percentage of medical groups across the country.

Other commenters noted they do not support a requirement that physician practices be certified as a primary care medical home to receive payment for chronic care management. Other commenters urged elimination of this requirement, noting it is too burdensome and would disqualify many practices furnishing these care coordination services. Commenters believe that in general, medical societies have been reluctant to accept proposals that would require medical homes or patient-centered practices to obtain accreditation/recognition by external entities; and therefore, urged CMS to work with the medical community to develop an alternative to accreditation as a path for furnishing chronic care management services. Other commenters noted this approach ignores the fact that many patients—especially the poor—do not have a primary care provider and by default, may receive substantial services from the Emergency Department, especially when other sources of primary care are unavailable or inaccessible. Some commenters conveyed that many standards for accreditation as a patient centered medical home do not consider the needs of those with dementia; adding, accreditation bodies should include quality measures on dementia care as a standard for accreditation. Some commenters encouraged CMS to consider using QIOs to help determine if a provider is meeting the requirements for chronic care management, instead of relying on a formal recognition program.

Some commenters noted that, instead of requiring any particular certification or designation, any physician practice should be able to qualify for payment of chronic care management services as long as the individual practice meets the practice requirements established to report these individual codes. Other commenters recommended that CMS instead require practices to have certain capabilities (that is, 24/7 access to care, 24/7 access to the individual's medical record, those involved with the care of a patient are identified and accessible, the health risk assessment data be addressed in the care of the patient, etc.); moreover, commenters suggested that CMS should clearly articulate that the ultimate goal is for primary care practices to achieve patient-centered medical home certification by a certain date (for instance 2019) as this would satisfy the agency's intention without being overly restrictive. Commenters also recommended that if CMS decides to recognize certified medical homes—through accreditation organizations or otherwise—the certification standards should fully reflect the Joint Principles for the

Patient-Centered Medical Home (http://tinyurl.com/ccbhvzz). Some commenters noted that requiring practice certification, such as that offered by NCQA for Patient-Centered Medical Homes, will undoubtedly limit access to chronic care management services for many beneficiaries, especially those in smaller practices and rural areas; and recommended CMS not make additional voluntary certifications mandatory, but rather look to those voluntary standards as it collaborates with the medical professional community to develop robust standards for chronic care management. Other commenters urged CMS to consider allowing practices to self-attest that they meet the protocol. Some commenters believe there needs to be an accountability mechanism for chronic care management which goes beyond "standards," such as quality measures that demonstrate improved outcomes and benefits for relevant patients.

Response: We appreciate commenters' suggestions and will consider these comments for any future rulemaking on this topic.

4. Billing for Separately Payable Chronic Care Management Services

To recognize the additional resources required to provide chronic care management services to patients with multiple chronic conditions, we proposed to create two new separately payable alphanumeric G-codes.

Complex chronic care management services furnished to patients with multiple (two or more) complex chronic conditions expected to last at least 12 months, or until the death of the patient, that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline;

GXXX1, initial services; one or more hours; initial 90 days

GXXX2, subsequent services; one or more hours; subsequent 90 days

Typically, we would expect the one or more hours of services to be provided by clinical staff directed by a physician or other qualified health care professional.

We also proposed that billing for subsequent chronic care management services (GXXX2) would be limited to those 90-day periods in which the medical needs of the patient require substantial revision of the care plan.

We proposed that the resources required to furnish care management services for patients that do not have multiple chronic conditions would continue to be reflected in the payment for face-to-face E/M services. We also proposed that the resources required to furnish care management services consisting of less than one or more hours of clinical staff time over a 90-day period, and for patients residing in facility settings, would continue to be reflected in the payment for face-to-face E/M visits.

We proposed that chronic care management services would include transitional care management services (CPT 99495, 99496), home health care supervision (HCPCS G0181), and hospice care supervision (HCPCS G0182). If furnished, to avoid duplicate payment, we proposed that these services may not be billed separately during the 90 days for which either GXXX1 or GXXX2 are billed. For similar reasons, we proposed that GXXX1 or GXXX2 cannot be billed separately if ESRD services (CPT 90951-90970) are billed during the same 90 days.

We proposed to pay only one claim for chronic care management services billed per beneficiary at the conclusion of each 90-day period.

We proposed that all of our proposed chronic care management services that are relevant to the patient must be furnished to bill for a 90-day period.

If a face-to-face visit is provided during the 90-day period by the practitioner who is furnishing chronic care management services, we proposed that the practitioner should report the appropriate evaluation and management code in addition to billing for chronic care management.

We note that to bill for these services, we proposed that at least 60 minutes of chronic care management services must be provided during a 90-day period. Time of less than 60 minutes over the 90 day period could not be rounded up to 60 minutes to bill for these services.

We also proposed that for purposes of meeting the 60-minute requirement, the practitioner could count the time of only one clinical staff member for a particular segment of time, and could not count overlapping intervals such as when two or more clinical staff members are meeting about the patient.

Comment: Many commenters requested that we either adopt the current CPT codes (CPT 99487-99489) for complex chronic care coordination services or work with the AMA to revise the current CPT codes rather than establish G-codes. Commenters also requested that we shorten the billing period from 90 days to 30 days, monthly, or weekly out of concern that it would be administratively burdensome for some practices to keep track of the amount of time they had furnished the service over a 90-day period. Many commenters also encouraged us to reconsider the need for separate G-codes for the initial delivery of chronic care management services versus subsequent delivery of these services since these commenters indicated that the resource use is similar. Some commenters supported our proposal that if a face-to-face visit is provided during the period by the practitioner who is furnishing chronic care management services, the practitioner should report the appropriate E/M code in addition to billing for chronic care management. Some commenters requested that we consider creating codes for chronic care management services to reflect different patient severity levels or create an add-on code, similar to the current CPT add-on code for 30 minutes of additional time (CPT 99489), that recognizes additional time for more complex patients within the eligible patient population. Some commenters agreed with our proposal that time less than the time specified in the code (60 minutes in our proposal) could not be rounded up to bill for these services. Some commenters also requested that we provide more detailed billing information for the services.

Response: Regarding the suggestion to work with CPT to avoid the need to establish G-codes, since we expect to implement payment for chronic care management services in 2015, there is time for CPT to establish a billing code that sufficiently reflects our policy. We would consider using such a new or revised code. The current CPT codes do not meet our policy requirements (for example, the eligible patient population, the time required for the code); therefore, we are not adopting these codes in this final rule.

We agree with commenters who suggested that we shorten the billing period for chronic care management services from 90 days to 30 days to reduce the administrative timekeeping burden on practices. We believe that a weekly billing interval would increase the administrative billing burden and note that very few commenters supported this option relative to 30 day or monthly billing.

We also agree with commenters that the resources required to furnish the initial and subsequent services are not sufficiently different to require the establishment of separate codes to distinguish initial and subsequent services.

In response to commenters' concerns, we are adopting a 30-day billing interval for chronic care management services. Given the shorter 30-day period, we are establishing a billing code that corresponds to 20 minutes of service during the 30-day period. Similar to our proposal, at least 20 minutes of chronic care management services must be provided during the 30-day billing interval. Time of less than 20 minutes over the 30-day period could not be rounded up to 20 minutes to bill for these services. For purposes of meeting the 20-minute requirement, the practitioner could count the time of only one clinical staff member for a particular segment of time, and could not count overlapping intervals such as when two or more clinical staff members are meeting about the patient.

With respect to comments requesting that we consider creating billing codes for chronic care management services to reflect different patient severity levels or create an add-on code that recognizes additional time for more severe patients within the eligible patient population, we are not adopting such a coding structure at this time. As recognized by the vast majority of commenters, paying separately for non-face-to-face chronic care management services is a significant policy change. As we gain more experience with separate payment for this service, we may consider additional changes in the coding structure in future rulemaking.

In response to comments asking that we provide more detailed billing information for these services, we intend to provide guidance to our contractors and make any necessary revisions to the relevant manual provisions to implement the chronic care management policy.

In summary, to recognize the additional resources required to provide chronic care management services to patients with multiple chronic conditions, we will be creating one new separately payable alphanumeric G-code for CY 2015.

GXXX1 Chronic care management services furnished to patients with multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline; 20 minutes or more; per 30 days

Typically, we would expect that the 20 minutes or more of chronic care management services to be provided by clinical staff directed by a physician or other qualified health care professional.

At least 20 minutes of chronic care management services must be provided during the 30-day period. Time of less than 20 minutes over the 30-day period may not be rounded up to 20 minutes in order to bill for these services. For purposes of meeting the 20-minute requirement, the practitioner could count the time of only one clinical staff member for a particular segment of

time, and could not count overlapping intervals such as when two or more clinical staff members are meeting about the patient.

We would consider using a revised CPT code that meets our policy requirements instead of creating a new G-code.

Comment: Some commenters stated that limiting the use of the billing code for subsequent delivery of chronic care management services to those circumstances in which the beneficiary requires "substantial revision of the care plan" undervalues the work the practitioner and practice care team does in furnishing ongoing assistance to beneficiaries in monitoring and implementing their care plans. Some commenters indicated that this restriction would reduce the potential benefits of chronic care management to the patient since in the absence of separate payment the services might be provided too intermittently. Other commenters, however, supported the restriction to time periods when the care plan has undergone significant revision since they believed that separately billable chronic care management should be for intense services delivered over a short period of time. Generally, these commenters were also ones who also favored narrowing the eligible patient population.

Response: As we stated in the discussion of the eligible patient population, we believe the resources required to furnish chronic care management services to beneficiaries with two or more chronic conditions are not adequately reflected in the existing E/M codes. We agree with commenters who argued that these resources could potentially be required during periods of time when the care plan is not undergoing substantial revision.

Therefore, after considering all the comments received, we are revising our proposed policy to specify that the chronic care management service may be billed for periods in which the

medical needs of the patient require establishing, implementing, revising, or monitoring the care plan, assuming all other billing requirements are met.

Comment: Some commenters objected to our proposal that chronic care management services include transitional care management services (CPT 99495, 99496), home health care supervision (HCPCS G0181), and hospice care supervision (HCPCS G0182) and that these services cannot be billed separately during the time period when the chronic care management services are billed. Some commenters also objected to our proposal that chronic care management services cannot be billed separately if certain ESRD services (CPT 90951-90970) are billed during the same time period. Some commenters believed that there was insufficient overlap between the resources required to perform these services and chronic care management to justify restricting the billing in the manner we proposed. Other commenters indicated that more than one practitioner should be allowed to bill for chronic care management services for the same time period.

Response: Given that, in response to comments, we have modified our new separately payable alphanumeric G-code for chronic care management services to describe services furnished for 20 minutes or more over a 30-day period, it may not always be the case that the additional resources required to provide chronic care management services to beneficiaries with multiple chronic conditions are the same as the additional resources required provide transitional care management services (CPT 99495, 99496), home health care supervision (HCPCS G0181), hospice care supervision (HCPCS G0182), or certain ESRD services (CPT 90951-90970).

Nevertheless, given that care management is an integral part of all of these services, we believe there is significant overlap, and that paying separately both for chronic care management and the care management included in these services would result in duplicate payment for the

overlapping care management. Similarly, allowing multiple practitioners to bill for GXXX1 during a particular billing interval would result in duplicate payment for overlapping care management. Therefore, we are finalizing our policy that GXXX1 and any of CPT 99495-99496, HCPCS G0181-G0182, or CPT 90951-90970 cannot be billed during the same 30-day period; nor can GXXX1 be billed by multiple practitioners for the same time period.

<u>Comment</u>: Some commenters objected to our proposal that the resources required to provide care management services to patients residing in facility settings continues to be reflected in the payment for face-to-face E/M visits. Commenters believed there was insufficient overlap between the scope of these care management services and the care management services provided by facilities to justify restricting the billing in the manner we proposed.

Response: We disagree with these comments. The resources required to provide care management services to patients residing in facility settings significantly overlaps with care management activities by facility staff that is included in the associated facility payment. We are finalizing this part of our proposal without modification.

<u>Comment</u>: MedPAC recommended that practitioners employed or furnishing services under arrangement with hospice or home health agencies should not be eligible to bill for these chronic care management services, citing the Medicare claims processing manual requirements for care plan oversight services.

Response: There is a requirement in the Medicare Claims Processing Manual (see http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c12.pdf) for hospice care plan oversight (CPO) that states:

"The attending physician or nurse practitioner (who has been designated as the attending physician) may bill for hospice CPO when they are acting as an 'attending physician.' An

'attending physician' is one who has been identified by the individual, at the time he/she elects hospice coverage, as having the most significant role in the determination and delivery of their medical care. They are not employed nor paid by the hospice."

We will consider MedPAC's comment further, but are not adopting this suggestion at the current time. We note that, as stated earlier in this section, home health care supervision (HCPCS G0181) and hospice care supervision (HCPCS G0182) cannot be billed separately during the time period when the chronic care management services are billed.

<u>Comment</u>: Many commenters requested that we clarify that billing for chronic care management is not restricted to primary care physicians and that specialist physicians can bill for these services if they meet the requirements. Some non-physician practitioners similarly requested confirmation that they can bill for these services if they meet the requirements.

Response: We appreciate these comments and take this opportunity to confirm that, while we expect the chronic care management code to be billed most frequently by primary care physicians, specialists who meet the requirements may also bill for these services. As for nonphysician qualified health care professionals, we believe only NPs, PAs, CNSs, and certified nurse midwives (CNMs) can furnish the full range of these services under their Medicare benefit, and only to the extent permitted by applicable limits on their state scope of practice. We believe other nonphysician practitioners (such as registered dieticians, nutrition professionals or clinical social workers) or limited-license practitioners, (such as optometrists, podiatrists, doctors of dental surgery or dental medicine), would be limited by the scope of their state licensing or their statutory Medicare benefit to furnish the complete scope of these services such that they would not be able to furnish chronic care management services; and there is no Medicare benefit

category that allows payment under the PFS to some of the other health professionals (such as pharmacists and care coordinators) mentioned by commenters.

We also note that given our longstanding restriction on the use of E/M codes by clinical psychologists and the fact that payment for these chronic care management services is currently included in the payment for E/M services, clinical psychologists are also not permitted to bill for these services. However, similar to transitional care management, we expect practitioners furnishing chronic care management services to refer patients to psychologists and other mental health professionals as part of chronic care management when doing so is warranted by an evaluation of the patient's psychosocial needs.

5. Obtaining Agreement from the Beneficiary

We stated in the proposed rule that not all patients who are eligible for separately payable chronic care management services may necessarily want these services to be provided.

Therefore, before the practitioner can furnish or bill for these services, we proposed that the eligible beneficiary must be informed about the availability of the services from the practitioner and provide his or her consent, or synonymously in this context "agreement," to have the services provided, including the electronic communication of the patient's information with other treating providers as part of care coordination. This would include a discussion with the patient about what chronic care management services are, how these services are accessed, how their information will be shared among other providers in the care team, and that cost-sharing applies to these services even when they are not delivered face-to-face in the practice. To bill for the services, the practitioner would be required to document in the patient's medical record that all of the chronic care management services were explained and offered to the patient, noting the patient's decision to accept these services. Also, a written or electronic copy of the care plan

would be provided to the beneficiary and this would also be recorded in the beneficiary's electronic medical record.

We proposed that a practitioner would need to reaffirm with the beneficiary at least every 12 months whether he or she wishes to continue to receive chronic care management services during the following 12-month period.

We proposed that the agreement for chronic care management services could be revoked by the beneficiary at any time. However, if the revocation occurs during a current chronic care management period, the revocation would not be effective until the end of that period. The beneficiary could notify the practitioner either verbally or in writing. At the time the agreement is obtained, the practitioner would be required to inform the beneficiary of the right to stop the chronic care management services at any time and the effect of a revocation of the agreement on chronic care management services. Revocation by the beneficiary of the agreement must also be noted by recording the date of the revocation in the beneficiary's medical record and by providing the beneficiary with written confirmation that the practitioner would not be providing chronic care management services beyond the current period.

We proposed that a beneficiary who has revoked the agreement for chronic care management services from one practitioner may choose instead to receive these services from a different practitioner, which can begin at the conclusion of the current period. The new practitioner would need to fulfill all the requirements for billing these services.

We proposed that prior to submitting a claim for chronic care management services, the practitioner must notify the beneficiary that a claim for these services will be submitted to Medicare. The notification must indicate: that the beneficiary has been receiving these services over the previous period (noting the beginning and end dates for the period); the reason(s) why

the services were provided; and a description of the services provided. The notice may be delivered by a means of communication mutually agreed to by the practitioner and beneficiary such as mail, email, or facsimile, or in person (for example, at the time of an office visit). The notice must be received by the beneficiary before the practitioner submits the claim for the services. A separate notice must be received by the beneficiary for each period for which the services will be billed. A copy of the notice should be included in the medical record.

<u>Comment</u>: While most commenters endorsed the general concept that that there should be a process whereby a practitioner would obtain agreement from an eligible beneficiary for the delivery of the service, we received comments on specific aspects of our proposal.

Some commenters supported our beneficiary agreement policies as proposed. Other commenters believed that notifying the beneficiary would be sufficient and that a formal agreement should not be required. Some commenters raised concern about the burden of having to obtain an annual agreement rather than obtaining just one agreement at the outset of furnishing the services. Many commenters recommended that CMS remove the requirement that practitioners notify beneficiaries in writing prior to each billing for chronic care management services, while other commenters supported this requirement. The commenters opposed to the pre-billing notification requirement viewed this as administratively burdensome and unnecessary given the informed agreement process for this service. Some commenters indicated that beneficiary agreement would be much easier to obtain if the service were not subject to coinsurance. Many commenters requested that we provide beneficiary education on this issue.

Response: We appreciate commenters recognizing the value of our requiring practitioners to inform beneficiaries about their eligibility to receive chronic care management services. We note that we do not have the statutory authority to waive the cost-sharing for these services. Since beneficiaries who receive these services will be billed for cost-sharing, we believe it is prudent to

require their written agreement prior to initiating the service. We agree that to reduce administrative burden, the informed agreement process need only occur once at the outset of furnishing the service, rather than annually as we had proposed, and that it only needs to be repeated if the beneficiary opts to change the practitioner who is delivering the services. We also agree with commenters who suggested that we relax the requirement that a practice inform a beneficiary prior to each time a bill is submitted. While we believe that this approach could reduce any potential confusion around cost-sharing charges, we agree that practitioners can address this in the informed agreement process.

In response to comments recommending that we educate beneficiaries about chronic care management services, we note that we provide extensive beneficiary education regarding Medicare benefits, including Medicare and You and other publications, Medicare.gov, and 1-800-MEDICARE. We will include information concerning chronic care management in our outreach efforts.

The final beneficiary agreement requirements for CY 2015 are as follows. Before the practitioner can furnish or bill for these services, the eligible beneficiary must be informed about the availability of the services from the practitioner and provide his or her written agreement to have the services provided, including agreeing to the electronic communication of the patient's information with other treating providers as part of care coordination. This would include a discussion with the patient, and caregiver when applicable, about what chronic care management services are, how these services are accessed, how the patient's information will be shared among other providers in the care team, and that cost-sharing applies to these services even when they are not delivered face-to-face in the practice. To bill for the services, the practitioner would be required to document in the patient's medical record that all of the chronic care management

services were explained and offered to the patient, noting the patient's decision to accept these services. Also, a written or electronic copy of the care plan is required to be provided to the beneficiary, and the provision of the plan to the patient must also be recorded in the beneficiary's electronic medical record.

The agreement for chronic care management services could be revoked by the beneficiary at any time. However, if the revocation occurs during a current chronic care management 30-day period, the revocation is not effective until the end of that period. The beneficiary could notify the practitioner of revocation either verbally or in writing. At the time the agreement is obtained, the practitioner is required to inform the beneficiary of the right to stop the chronic care management services at any time (effective at the end of a 30-day period) and the effect of a revocation of the agreement on chronic care management services. The practitioner is also required to inform the beneficiary that only one practitioner is able to be separately paid for these services during the 30-day period. Revocation by the beneficiary of the agreement must also be noted by recording the date of the revocation in the beneficiary's medical record and by providing the beneficiary with written confirmation that the practitioner would not be providing chronic care management services beyond the current 30-day period.

A beneficiary who has revoked the agreement for chronic care management services from one practitioner may choose instead to receive these services from a different practitioner, which can begin at the conclusion of the current 30-day period. If a beneficiary chooses to receive these services from a different practitioner, the beneficiary should revoke the agreement with the current practitioner. The new practitioner would need to fulfill all the requirements for billing these services.

5. Chronic Care Management Services and the Annual Wellness Visit (AWV) (HCPCS codes G0438, G0439)

We proposed that a beneficiary must have received an AWV in the past 12 months for a practitioner to be able to bill separately for chronic care management services. We believe that the linking of these services to the AWV makes sense for several reasons. First, the AWV is

designed to enable a practitioner to systematically capture information that is essential for the development of a care plan. This includes the establishment of a list of current practitioners and suppliers that are regularly involved in providing medical care to the beneficiary, the assessment of the beneficiary's functional status related to chronic health conditions, the assessment of whether the beneficiary suffers from any cognitive limitations or mental health conditions that could impair self-management of chronic health conditions, and an assessment of the beneficiary's preventive health care needs including those that contribute to or result from a beneficiary's chronic conditions. Second, the beneficiary's selection of a practitioner to furnish the AWV is a useful additional indicator to assist us in knowing which single practitioner a beneficiary has chosen to furnish chronic care management services. Although a beneficiary would retain the right to choose and change the practitioner to furnish chronic care management services, we do not believe that it is in the interest of a beneficiary to have more than one practitioner at a time coordinating the beneficiary's care and we do not intend to pay multiple practitioners for furnishing these services over the same time period. Third, the AWV is updated annually which is consistent with the minimal interval for reviewing and modifying the care plan required for the chronic care management services.

We would expect that the practitioner the beneficiary chooses for the AWV would be the practitioner furnishing the chronic care management services. For the less frequent situations when a beneficiary chooses a different practitioner to furnish the chronic care management services from the practitioner who in the previous year furnished the AWV, the practitioner furnishing the chronic are management services would need to obtain a copy of the assessment and care plan developed between the beneficiary and the practitioner who furnished the AWV prior to billing for chronic care management services.

Because a beneficiary is precluded from receiving an AWV within 12 months after the effective date of his or her first Medicare Part B coverage period, for that time period we proposed the Initial Preventive Physical Examination (G0402) can substitute for the AWV to allow a beneficiary to receive chronic care management services.

Comment: Although some commenters supported our proposal, there were numerous comments recommending that we remove the requirement for an Annual Wellness Visit prior to a practitioner being able to furnish chronic care management services. While some commenters acknowledged that the Annual Wellness visit could provide valuable information for establishing a care plan and for ensuring that only one practitioner billed for the chronic care management services, many expressed concern that this could present a significant barrier to otherwise eligible beneficiaries receiving the services.

Response: We believe that both the practitioner and the beneficiary would benefit if an AWV or an Initial Preventive Physical Examination (IPPE) occurs at the outset of chronic care management services. It would allow the practitioner to systematically gather information that can inform the care plan and it would allow the beneficiary the opportunity to address questions and concerns about wellness issues that may be important for those with multiple chronic conditions. With their required services, the IPPE or AWV assures that at least once a year there is a focus on the broad wellness aspects of care, which can easily be dominated by the more chronic conditions when they exist. In addition to the clinical benefits of the AWV or IPPE, these services provide administrative benefits as well. They allows us to know the one practitioner the beneficiary has chosen to furnish chronic care management services and assure that multiple practitioners cannot provide the service to the same patient. However, in light of the widespread concerns raised by commenters about this requirement, we have changed the

requirement to a recommendation for a practitioner to furnish an AWV or IPPE to a beneficiary prior to billing for chronic care management services furnished to that same beneficiary. As an alternative, a practitioner who meets the practice standards that will be established to bill for chronic care management services may initiate services with an eligible beneficiary as a part of an AWV, an IPPE, or a comprehensive E/M visit.

6. Chronic Care Management Services Furnished Incident to a Physician's Service under General Physician Supervision

In the proposed rule, we discussed the requirements for billing for services furnished in the office, but not personally and directly performed by the physician or qualified nonphysician practitioner (referred to as a "practitioner" in the following discussion), under our "incident to" requirements at 410.26 and in section 60, Chapter 15, of Medicare Benefit Policy Manual (100-02). One key requirement of "incident to" services is that a physician directly supervise the provision of services by auxiliary personnel by being in the office suite and be immediately available to furnish assistance and direction throughout the provision of the service. Section 60.4 of the Manual specifically discusses the one exception, which allows for general supervision of "incident to" services furnished to homebound patients in medically underserved areas. Under that exception, we identify more specific requirements for the personnel who can provide "incident to" services under general supervision. For example, we require that the personnel must be employed by the physician billing the "incident to" services.

One of the required capabilities for a physician to furnish chronic care management services is 24-hour-a-day, 7-day-a-week beneficiary access to the practice to address the patient's chronic care needs. We would expect that the patient would be provided with a means to make timely contact with health care providers in the practice when necessary to address chronic care needs regardless of the time of day or day of the week. If the patient has a chronic care need outside of the practice's normal business hours, the patient's initial contact with the practice to address that need could be with clinical staff

employed by the practice, (for example, a nurse) and not necessarily with a physician. Those services could be furnished incident to the services of the billing physician.

We also proposed to require a minimum amount of time of chronic care services be furnished to a patient during a period for the physician to be able to bill separately for the chronic care services. The time, if not personally furnished by the physician, must be directed by the physician. We proposed that the time spent by a clinical staff person providing aspects of chronic care services outside of the practice's normal business hours during which there is no direct supervision would count towards the time requirement even though the services do not meet the direct supervision requirement for "incident to" services.

We stated our belief that the additional requirements we impose for auxiliary personnel under the exception for general supervision for homebound patients in medically underserved areas should apply in these circumstances where we are allowing a physician to bill Medicare for chronic care management services furnished under their general supervision and incident to their professional services. In both of these unusual cases, these requirements help to ensure that appropriate services are being furnished by appropriate personnel in the absence of the direct supervision. Specifically, we proposed that if a practice meets all the conditions required to bill separately for chronic care management services, the time spent by a clinical staff employee providing aspects of these services to address a patient's chronic care need outside of the practice's normal business hours can be counted towards the time requirement when at a minimum the following conditions are met:

- The clinical staff person is directly employed by the physician
- The services of the clinical staff person are an integral part of the physician's chronic care management services to the patient (the patient must be one the physician is treating and for which an informed agreement is in effect), and are performed under the general supervision of the physician. General supervision means that the physician need not be physically present when the services are performed; however, the services must be performed under the physician's overall supervision and control. Contact is maintained between the clinical staff person and the physician (for example, the

employed clinical staff person contacts the physician directly if warranted and the physician retains professional responsibility for the service.)

• The services of the employed clinical staff person meet all other "incident to" requirements, compliance with applicable state law, with the exception of direct supervision.

Comment: The vast majority of commenters supported the idea of general rather than direct supervision, although we did receive comments on specific aspects of our proposal. A few commenters said they recognized the difficulties in making exceptions to the "incident to" policies. Some commenters supported the proposal as stated in the proposed rule. Many commenters objected to the proposed requirement that the clinical staff person be directly employed by the physician, indicating that this would be a barrier to widespread adoption of the policy. Some commenters requested that we remove the employment requirement entirely, especially given that eligible practices will need to meet certain standards to be able to separately bill for chronic care management services. Other commenters indicated that if CMS were to keep the employment requirement it should be modified to allow the clinical staff person to be an employee of the physician or an employee of the practice. Some commenters recommended that the policy be modified to allow the clinical staff person be either an employee or an independent contractor. These commenters stated a distinction between the clinical staff person as an independent contractor and having the services provided under arrangement since typically the practice would directly supervise the contracted individual. A few commenters stated that a requirement to have all possible chronic care management services provided by employees would undermine access to these services. Some commenters indicated that CMS should allow general rather than direct supervision for more situations, not just time spent by clinical staff outside of the practices normal business hours. For example, one commenter indicated that time spent by clinical staff providing chronic care management services to homebound patients in the patient's homes should count towards the time requirement if provided under general supervision. Some commenters expressed concern that our use of the word "physician" in this discussion could potentially create confusion that we are not also referring to qualified non-physician practitioners.

Response: We appreciate the general support for our proposal as well as the recognition by some commenters of the challenges presented by the issue of an exception to "incident to related requirements," even for this unusual case. We agree with the commenters who supported our policy as stated in the proposed rule since we continue to believe that within eligible practices the employment requirement helps ensure that appropriate services are being furnished by appropriate personnel under the lesser requirement of general supervision. We are clarifying that the clinical staff person furnishing the chronic care management services could be employed either by the physician or the practice.

Given the potential risk to the patient that exceptions to the direct physician supervision requirement could create, we believe it is appropriate to proceed deliberately in this area. We believe that this exception in this unusual case should be designed as narrowly as possible while still facilitating the chronic care management policy. Therefore, we disagree at the current time with commenters who requested broader exceptions to the direct physician supervision requirement to remove the employment requirement entirely, to include independent contractors, or to include other situations for CY 2015.

In response to commenters who stated that a requirement to have all possible chronic care management services provided by employees would undermine access to these services, we note that we did not propose such a requirement. Our proposed employment requirement was limited to allowing the time spent by a clinical staff employee in providing aspects of chronic care management services to address a patient's chronic care need outside of the practice's normal business hours to count towards the time requirement for these services to be separately billed. To bill for "incident to" services, practitioners should follow all the usual "incident to" requirements except when furnishing services outside of normal business hours under conditions that meet the requirements for the general supervision exception as described above.

We also note that our "incident to" policies apply to all practitioners who can bill Medicare directly for services, and thus apply to physicians and other nonphysician practitioners. As discussed in section II.J, we are aligning the requirements for "incident to" services to make clear that all practitioners

who can bill Medicare for "incident to" services are subject to the same regulations at 410.26. We intend that the exception to the direct supervision requirement for after-hours chronic care management services furnished on an "incident to" basis will apply to all practitioners who can bill Medicare for services incident to their services and who can provide chronic care management services.

In summary, we are finalizing our proposal for CY 2015 without modification except for our clarification that the clinical staff person furnishing the chronic care management services could be employed either by the physician or the practice.

In light of the concerns by some commenters that our use of the word "physician" in this discussion could potentially create confusion that we are not also referring to qualified non-physician practitioners, we reiterate that, as we stated in the proposed rule, "physician" in this discussion also refers to qualified non-physician practitioners.

7. Chronic Care Management Services and the Primary Care Incentive Payment Program (PCIP)

Under section 1833(x) of the Act, the PCIP provides a 10 percent incentive payment for primary care services within a specific range of E/M services when furnished by a primary care physician. Specific physician specialties and qualified nonphysician practitioners can qualify as primary care practitioners if 60 percent of their PFS allowed charges are primary care services. As we explained in the CY 2011 PFS final rule (75 FR 73435 through 73436), we do not believe the statute authorizes us to add codes (additional services) to the definition of primary care services. However, to avoid inadvertently disqualifying community primary care physicians who follow their patients into the hospital setting, we finalized a policy to remove allowed charges for certain E/M services furnished to hospital inpatients and outpatients from the total allowed charges in the PCIP primary care percentage calculation. In the CY 2013 final rule (77 FR 68993), we adopted a policy that the TCM code should be treated in the same manner as those services for the purposes of PCIP because post-discharge TCM services are a complement in the community setting to the hospital-based discharge day management services already excluded from the PCIP denominator. Similar to the codes already excluded from the PCIP denominator, we expressed concern that inclusion of the TCM code in the denominator of the primary care percentage

calculation could produce unwarranted bias against "true primary care practitioners" who are involved in furnishing post-discharge care to their patients.

Chronic care management services are also similar to the services that we have already excluded from the from the PCIP denominator. For example, chronic care management includes management of care transitions within health care settings including referrals to other clinicians, visits following a patient visit to an emergency department, and visits following discharges from hospitals and skilled nursing facilities. Therefore, while physicians and qualified nonphysician practitioners who furnish chronic care management services would not receive an additional incentive payment under the PCIP for the service itself (because it is not considered a "primary care service" for purposes of the PCIP), we proposed that the allowed charges for chronic care management services would not be included in the denominator when calculating a physician's or practitioner's percent of allowed charges that were primary care services for purposes of the PCIP.

<u>Comment</u>: Many commenters supported, and no commenters opposed, our proposed treatment of chronic care management services in the PCIP calculation given that these services are not eligible for the incentive payment under the PCIP.

Response: We agree with the commenters and are finalizing our proposal for CY 2015 without modification.

L. Collecting Data on Services Furnished in Off-Campus Provider-Based Departments

As we discussed in the CY 2014 PFS proposed rule (78 FR 43301) and CY 2014 OPPS/ASC proposed rule (78 FR 43626), in recent years, the research literature and popular press have documented the increased trend toward hospital acquisition of physician practices, integration of those practices as a department of the hospital, and the resultant increase in the delivery of physicians' services in a hospital setting (for example, we refer readers to Ostrom, Carol M., "Why you might pay twice for one visit to a doctor," Seattle Times,

November 3, 2012, and O'Malley, Ann, Amelia M. Bond, and Robert Berenson, Rising hospital employment of physicians: better quality, higher costs? Issue Brief No. 136, Center for Studying Health System Change, August 2011).

When a Medicare beneficiary receives outpatient services in a hospital, the total payment amount for outpatient services made by Medicare is generally higher than the total payment amount made by Medicare when a physician furnishes those same services in a freestanding clinic or in a physician's office. As more physician practices become hospital-based, news articles have highlighted beneficiary liability that is incurred when services are furnished in a hospital-based physician practice. MedPAC has questioned the appropriateness of increased Medicare payment and beneficiary cost-sharing when physicians' offices become hospital outpatient departments and has recommended that Medicare pay selected hospital outpatient services at the MPFS rates (MedPAC March 2012 Report to Congress; "Addressing Medicare Payment Differences across Settings," presentation to the Commission on March 7, 2013).

The total payment generally is higher when outpatient services are furnished in the hospital outpatient setting rather than a freestanding clinic or a physician office. When a service is furnished in a freestanding clinic or physician office, only one payment is made under the

MPFS; however when a service is furnished in a hospital-based office. Medicare pays the hospital a "facility fee" and a payment for the physician portion of the service, which is a lower payment than if the service would have been furnished in a physician's office. Although the physician payment is lower when the services are furnished in a hospital, the total payment (facility fee and physician fee) is generally more than the Medicare payment if the same service was furnished in a freestanding clinic or physician office. The beneficiary pays coinsurance for both the physician payment and the hospital outpatient payment (facility fee). Upon acquisition of a physician practice, hospitals frequently treat the practice locations as off-campus providerbased departments of the hospital and bill Medicare for services furnished at those locations under the OPPS. (For further information on the provider-based regulations at §413.65, we refer readers to http://www.gpo.gov/fdsys/pkg/CFR-2010-title42-vol2/pdf/CFR-2010-title42-vol2sec413-65.pdf). Since October 1, 2002, we have not required hospitals to seek from CMS a determination of provider-based status for a facility that is located off campus. We also do not have a formal process for gathering information on the frequency, type, and payment of services furnished in off-campus provider-based departments of the hospital.

We stated in the CY 2014 proposed rules that in order to better understand the growing trend toward hospital acquisition of physician offices and subsequent treatment of those locations as off-campus provider-based outpatient departments, we were considering collecting information that would allow us to analyze the frequency, type, and payment of services furnished in off-campus provider-based hospital departments. We stated that we have considered several potential methods. Claims-based approaches could include (1) creating a new place of service code for off campus departments of a provider under §413.65(g)(2) as part of item 24B of the CMS–1500 claim form, comparable to current place of service codes such as

"22 Outpatient" and "23 Emergency Room-Hospital" when physician services are furnished in an off-campus provider-based department, or (2) creating a HCPCS modifier that could be reported with every code for services furnished in an off-campus provider-based department of a hospital on the CMS-1500 claim form for physician services and the UB-04 (CMS form 1450) for hospital outpatient claims. In addition, we have considered asking hospitals to break out the costs and charges for their provider-based departments as outpatient service cost centers on the Medicare hospital cost report, form 2552-10. We noted that some hospitals already break out these costs voluntarily or because of cost reporting requirements for the 340B Drug Discount Program, but this practice is not consistent or standardized. In the proposed rules, we invited public comments on the best means for collecting information on the frequency, type, and payment of services furnished in off-campus provider-based departments of hospitals.

Comment: Although most commenters agreed on the need to collect information on the frequency, type, and payment for services furnished in off-campus provided-based departments of hospitals, opinions differed on how to best collect this additional data. Some commenters preferred identifying services furnished in provider-based departments on the cost report, while others preferred one of the claims-based approaches. Some commenters supported either approach, noting the trade-offs in terms of the type of data that could be collected accurately and the administrative burden involved. Some suggested we convene a group of stakeholders to develop consensus on the best approach. Commenters generally recommended that CMS choose the least administratively burdensome approach that would ensure accurate data, but did not necessarily agree on what approach would optimally achieve that result. For example, limiting the data collection to cost report approaches results in little administrative burden for physicians

since they do not file cost reports, but could result in varying degrees of administrative effort for hospitals depending on the specific cost reporting requirements.

Several commenters noted that some hospitals already voluntarily identify costs specific to provider-based departments on their cost reports. Since cost and charge information is already reported separately, these commenters asserted there would be no additional burden, although additional variables or changes to the structure of the cost report may be required. In addition, the commenters noted that cost report information would be transparent and audited for accuracy. One commenter recommended aggregate reporting of all off-campus provider-based departments as one or several cost centers, and another indicated that CMS should consider assigning separate sub-provider numbers for off-campus departments similar to those used for rehabilitation and psychiatric units.

However, other commenters believed that a HCPCS modifier would more clearly identify specific services provided and would provide better information about the type and level of care furnished. Some commenters believed a HCPCS modifier would be the least administratively burdensome as hospitals and physicians already report a number of claims-based modifiers. However, other commenters used this same fact about the number of existing claims-based modifiers to argue that additional modifiers would increase administrative burden since it would increase the number of modifiers that needed to be considered when billing. These commenters and others recommended that CMS should consider the establishment of a new Place of Service (POS) code since they believed it would be less administratively burdensome than attaching a modifier to each service on the claim that was furnished in an off-campus provider-based department. Some commenters stated that establishing a new POS code would work better under the PFS than the OPPS since under the OPPS a single claim was more likely to contain lines for

services furnished in both on-campus and off-campus parts of the hospital on the same day for the same beneficiary.

MedPAC believes there may be some limited value in collecting data on services furnished in off-campus provider-based departments to validate the accuracy of site-of-service reporting when the physician office is off-campus but billing as an outpatient department, but did not recommend a particular data collection approach. MedPAC emphasized that any data collection effort should not prevent the development of policies to align payment rates across settings.

Response: We appreciate the public feedback in response to our comment solicitation in the proposed rules. We will take the comments received into consideration as we continue to consider approaches to collecting data on services furnished in off-campus provider-based departments.

M. Chiropractors Billing for Evaluation & Management Services

Section 1861(r)(5) of the Act includes chiropractors in its definition of "physician" with language limiting chiropractors to "treatment by means of manual manipulation of the spine (to correct a subluxation)." In accordance with the statute as we noted on page 43342 of the CY2014 proposed rule, chiropractic coverage, therefore, is limited to treatment of subluxation of the spine and payment can only be made for that purpose. Specifically, we make payment for only the following three codes listed in the chiropractic section of the CPT Manual:

98940 – Chiropractic manipulation treatment (CMT), spinal, 1-2 regions

98941 – CMT spinal, 3-4 regions

98942 - CMT spinal, 5 regions

We solicited comments in the CY2014 proposed rule regarding the appropriateness of the billing of E/M services by chiropractors although we did not propose to pay chiropractors for E/M services in 2014. We wanted to determine whether there are situations in which E/M services not included in Chiropractic Manipulative Treatment (CMT) codes 98940-98942 would meet the statutory requirements for chiropractic services and therefore, could be appropriately billed.

To achieve that goal, we asked that information be submitted regarding the following: the services that would be provided; the benefits that would accrue including whether access to chiropractic services for Medicare beneficiaries would be expanded; the justification for E/M services beyond those included in the CMT codes; the appropriateness of allowing billing for all office E/M codes for new or existing patients; the specific creation of one or a set of codes for chiropractic E/M services; the frequency that chiropractors should be allowed to bill E/M services; and the volume that could be expected.

Although very few commenters submitted comments that addressed all of the information we requested in the proposed rule, we do thank all the commenters for their input. Any possible changes to our current policy on allowing chiropractors to bill E/M services will be addressed in future notice and comment rulemaking.

III. Other Provisions of the Proposed Regulations

A. Medicare Coverage of Items and Services in FDA-Approved Investigational Device

Exemption Clinical Studies--Revisions of Medicare Coverage Requirements

- 1. Background and Statutory Authority
- a. General

Section 1862(m) of the Act (established by section 731(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173, enacted on December 8, 2003)) allows for payment of the routine costs of care furnished to Medicare beneficiaries in a Category A investigational device exemption (IDE) trial and authorizes the Secretary to establish criteria to ensure that Category A IDE trials conform to appropriate scientific and ethical standards. By providing Medicare coverage of routine costs in Category A trials, the Congress removed a financial barrier that may have discouraged beneficiaries from participating in these trials. It also gives Medicare beneficiaries the opportunity to have earlier access to new medical devices. However, the statute does not require Medicare to cover the Category A device itself. We note that throughout this section of the preamble, the words study and trial are used interchangeably.

(1) Category A IDE devices

For Category A IDE devices, existing §405.201(b) defines an "experimental/investigational (Category A) device" as an innovative device believed to be in Class III for which "absolute risk" of the device type has not been established (that is, initial questions of safety and effectiveness have not been resolved and the FDA is unsure whether the device type can be safe and effective). Existing §405.207(b)(2) states that payment may be made for the routine care services related to Category A IDE devices if, among other things, the services are furnished in conjunction with an FDA-approved clinical trial, and that the trial is

required to meet criteria established through the Medicare national coverage determination process.

(2) Category B IDE devices

Existing §405.201(b) defines a "non-experimental/investigational (Category B) device" as a device believed to be in Class I or Class II, or a device believed to be in Class III for which the incremental risk is the primary risk in question (that is, underlying questions of safety and effectiveness of that device type have been resolved), or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA approval for that device type. Existing §405.211 allows Medicare contractors to make coverage decisions for non-experimental/investigational (Category B) devices if certain requirements are met. If a Medicare contractor determines that a Category B device is covered, Medicare also covers routine care services related to a non-experimental/investigational (Category B) device furnished in conjunction with an FDA-approved clinical trial, per §405.207(b)(3). Based on our rulemaking authority in section 1871 of the Act, we proposed to apply the same Medicare coverage requirements and scientific and ethical standards to Medicare coverage related to Category B IDE studies/trials that would be applicable to Category A IDE studies/trials.

b. Background

We sought and received input from stakeholders (for example: manufacturers, study sponsors, and hospitals) regarding the Medicare coverage approval process for Category B IDE devices. The majority of stakeholders told us that obtaining Medicare coverage of the Category B IDE device and the costs of routine items and services is inefficient since local Medicare contractors have differing processes for reviewing IDE studies for purposes of Medicare coverage, which result in inconsistent Medicare coverage of Category B IDE devices and associated routine care services across the Medicare contractor jurisdictions. Stakeholders also

suggested that these factors contribute to their reluctance to enroll Medicare beneficiaries in IDE trials and studies, and that Medicare coverage variability between Medicare contractors made it difficult to conduct national IDE trials.

We also requested input from local Medicare contractors regarding their existing processes for determining coverage of Category B IDE devices and associated routine care services. They reported that they review pertinent available evidence and the FDA-approved IDE trial protocol as factors in their decision-making process to ensure that the device is reasonable and necessary for Medicare beneficiaries and furnished in appropriate settings. Local Medicare contractors apply varying levels of scrutiny to these factors. While most Medicare contractors extensively review IDE study protocols, other contractors may review them less extensively. Although there is variability among contractors, in many cases the review processes are duplicative in that multiple Medicare contractors are reviewing the same materials in the same way.

2. Summary of Provisions of the Proposed Regulation

We proposed to modify our regulations related to Medicare coverage of routine care items and services in Category A IDE studies and trials, and Medicare coverage of Category B IDE devices and routine care items and services. We proposed to establish criteria for IDE studies so that Category A IDE trials conform to appropriate scientific and ethical standards for Medicare coverage consistent with our authority under section 1862(m)(2)(B) of the Act. We proposed to extend the same Medicare coverage requirements to Medicare coverage of Category B IDE device trials, using our general rulemaking authority under section 1871 of the Act. We proposed that Medicare coverage decisions related to coverage of items and services in Category A and B IDE trials and studies be made by CMS centrally.

a. Proposed Definitions

We proposed to replace the definitions in §405.201(b) with the following:

• <u>Category A (Experimental) device</u>: A device for which "absolute risk" of the device type has not been established (that is, initial questions of safety and effectiveness have not been resolved) and the FDA is unsure whether the device type can be safe and effective.

- <u>Category B (Nonexperimental/investigational) device</u>: A device for which the incremental risk is the primary risk in question (that is, initial questions of safety and effectiveness of that device type have been resolved) or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA approval for that device type.
- <u>ClinicalTrials.gov</u>: The National Institutes of Health's National Library of Medicine's online registry and results database of publicly and privately supported clinical studies of human participants conducted around the world.
- <u>Contractors</u>: Medicare Administrative Contractors and other entities that contract with CMS to review and adjudicate claims for Medicare items and services.
- IDE stands for investigational device exemption: An FDA-approved IDE application permits a device, which would otherwise be subject to marketing approval or clearance, to be shipped lawfully for the purpose of conducting a clinical study in accordance with 21 U.S.C. 360j(g) and 21 CFR parts 812.
- <u>Pivotal studies or trials</u>: Clinical investigations designed to collect definitive evidence of the safety and effectiveness of a device for a specified intended use, typically in a statistically justified number of subjects. It may or may not be preceded by an early and/or a traditional feasibility study.
- Routine care items and services: Items and services that are otherwise generally available to Medicare beneficiaries (that is, a benefit category exists, it is not statutorily

excluded, and there is not a national noncoverage decision) that are furnished in either the experimental or the control arms of a clinical trial and that would be otherwise furnished even if the beneficiary were not enrolled in a clinical trial.

- <u>Superiority studies or trials</u>: Studies or trials that are intended to demonstrate at some prespecified level of confidence that the effect of an investigational treatment is superior to that of an active control by more than a prespecified margin.
- b. Proposed Provisions for Medicare coverage of items and services in FDA-approved IDE studies.

To ensure that Medicare coverage of items and services in Category A and B IDE studies is more consistent across Medicare administrative regions, we proposed that IDE coverage decisions be made by CMS centrally. We proposed a centralized IDE coverage review process for Category A and Category B IDEs, by adding §405.201(a)(3) stating that CMS identifies criteria for coverage of items and services furnished in IDE studies. We proposed to replace existing §405.211 with the following Medicare coverage requirements for items and services in Category A and Category B FDA-approved IDE studies.

- CMS will review the following items and supporting materials as needed: (1) the FDA approval letter, (2) IDE study protocol, (3) IRB approval letter(s), (4) ClinicalTrials.gov identifier.
- Medicare may cover routine care items and services furnished in any FDA-approved
 Category A IDE study if the criteria in proposed new §405.212(a) and (b) are met.
- Medicare covers a Category B IDE device and routine care items and services furnished in any FDA-approved Category B IDE study if the criteria in proposed new §405.212(a) and (c) are met.
 - If an IDE device is furnished in an FDA-approved IDE study that does not wholly fall

under proposed new §405.212(b) or (c), CMS considers whether the study's attainment of the criteria in proposed new §405.212(a) are sufficient to mitigate the failure to meet the criteria in proposed new §405.212(b) or (c).

We also proposed to notify the public of Medicare covered Category A and B IDE studies by posting the IDE study title and ClinicalTrials.gov identifier on the CMS coverage website and publishing a list of trials in the **Federal Register**. We stated that a centralized review process would be more efficient by reducing the burden for stakeholders interested in seeking Medicare coverage related to nationwide IDE studies or trials. Having a single entity making Medicare coverage decisions would enhance administrative efficiency by eliminating the need for duplicative submissions from stakeholders to different Medicare contractors and duplicative reviews by Medicare contractors. In the preamble to the proposed rule, we stated that we did not believe that the proposed coverage requirements would significantly change the number of items and services covered compared to coverage under existing requirements.

We stated in the preamble to the proposed rule that any interested party who seeks

Medicare coverage related to a Category A or B IDE study may send us a request letter that

describes the scope and nature of the Category A or B IDE study, discussing each of the criteria
in the proposed policy. Requests would be submitted via email to

<u>clinicalstudynotification@cms.hhs.gov</u> or via hard copy to the following address: Centers for

Medicare & Medicaid Services; Center for Clinical Standards & Quality; Director, Coverage and

Analysis Group; ATTN: Clinical Study Certification; Mailstop: S3-02-01; 7500 Security Blvd;

Baltimore, MD 21244.

c. Proposed Medicare Coverage IDE Study Criteria:

We proposed to add a new §405.212 that describes the Medicare coverage criteria that Category A and B IDE studies or trials must meet in order for Medicare to cover routine care

items and services in Category A IDE studies or trials, and for Medicare to cover Category B IDE devices and routine care items and services (per proposed revised §405.207 and §405.211). We proposed the following Medicare coverage IDE study criteria.

- (1) The principal purpose of the study is to test whether the item or service meaningfully improves health outcomes of patients who are represented by the Medicare-enrolled subjects.
- (2) The rationale for the study is well supported by available scientific and medical information, or it is intended to clarify or establish the health outcomes of interventions already in common clinical use.
 - (3) The study results are not anticipated to unjustifiably duplicate existing knowledge.
- (4) The study design is methodologically appropriate and the anticipated number of enrolled subjects is adequate to answer the research question(s) being asked in the study.
- (5) The study is sponsored by an organization or individual capable of completing it successfully.
- (6) The study is in compliance with all applicable Federal regulations concerning the protection of human subjects found at 45 CFR part 46.
- (7) All aspects of the study are conducted according to appropriate standards of scientific integrity set by the International Committee of Medical Journal Editors.
- (8) The study has a written protocol that clearly demonstrates adherence to the standards listed here as Medicare requirements.
- (9) Where appropriate, the clinical research study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Trials of all medical technologies measuring therapeutic outcomes as one of the objectives may be exempt from this standard only if the disease or condition being studied is life threatening as defined in 21 CFR 312.81(a) and the patient has no other viable treatment options.

(10) The study is registered on the ClinicalTrials.gov website and/or the Registry of Patient Registries (RoPR) by the principal sponsor/investigator prior to the enrollment of the first study subject.

- (11) The study protocol specifies the method and timing of public release of results on all pre-specified outcomes, including release of negative outcomes. The release should be hastened if the study is terminated early. The results must be made public within 24 months of the end of data collection. If a report is planned to be published in a peer reviewed journal, then that initial release may be an abstract that meets the requirements of the International Committee of Medical Journal Editors. However, a full report of the outcomes must be made public no later than 3 years after the end of data collection.
- (12) The study protocol explicitly discusses subpopulations affected by the item or service under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion criteria [a]ffect enrollment of these populations, and a plan for the retention and reporting of said populations in the study. If the inclusion and exclusion criteria are expected to have a negative effect on the recruitment or retention of underrepresented populations, the protocol must discuss why these criteria are necessary.
- (13) The study protocol explicitly discusses how the results are or are not expected to be generalizable to subsections of the Medicare population to infer whether Medicare patients may benefit from the intervention. Separate discussions in the protocol may be necessary for populations eligible for Medicare due to age, disability, or Medicaid eligibility.

We stated in the preamble to the proposed rule that all IDE investigational device studies where Medicare coverage is sought should conform to rigorous scientific and ethical standards. We believe that these criteria are essential to protecting Medicare study participants in Category A and Category B trials. Studies that have high scientific and ethical standards lead to

generalizable and reliable knowledge for the Medicare program including, providers, practitioners, and beneficiaries.

We believe that additional Medicare coverage criteria are needed for Category A and B IDE studies where Medicare coverage for items and services is sought, to ensure that the study design is appropriate to answer questions of importance to the Medicare program and its beneficiaries. Although an item or service may be considered appropriate when used by a clinician for the benefit of an individual patient, it may not be reasonable and necessary when used in the context of an IDE study or trial for purposes of Medicare coverage. The use of such a device in an IDE study or trial may expose study participants to increased risks that must be balanced by other factors, including the likelihood that the study would add important information to the body of medical knowledge relevant to the Medicare program.

While most studies are undertaken only after a detailed protocol has been developed, some are not. The protocol is the primary source of knowledge on the proposed design and management of the study. Without this document, reviewers and funding entities are unable to ascertain the quality and validity of the study, and whether the study is appropriate to answer questions of importance to the Medicare program. The exercise of committing to paper all the aspects of the study is crucial to ensuring that all potential concerns have been addressed.

We proposed these 13 Medicare coverage IDE study criteria because we believe they must be integral to any study that is approved for purposes of Medicare coverage. The proposed first four criteria and the seventh criterion were developed because they embody ethical values. The fifth and sixth proposed criteria were developed in response to reports of egregious misconduct in the past in endeavors to conduct clinical research by placing individuals at the risk of harm for the good of others.

In §405.211, we proposed that if the following two characteristics are also met, in

addition to the IDE study criteria listed in proposed new §405.212(a)(1) through (a)(13), we would automatically cover the costs of routine items and services in the Category A study or trial, and the costs of the investigational device and the routine items and services in a Category B study or trial as follows:

- The study is a pivotal study.
- The study has a superiority study design.

Existing §405.207(b)(2) requires that for Medicare coverage of related routine care services, all Category A IDE studies and trials must meet the criteria established through the NCD process. We proposed to modify §405.207(b) to remove the NCD process requirement and state that payment may be made for routine care items and services related to experimental/investigational (Category A) devices as defined in §405.201(b), and furnished in conjunction with an FDA-approved clinical trial that meets the Medicare coverage IDE study criteria in proposed new §405.212. We proposed to modify §411.15(o)(2) to specify that the exclusions from Medicare coverage include experimental or investigational devices, except for certain devices furnished in accordance with the Medicare coverage requirements proposed in revised §405.211.

3. Summary of Public Comments

We received 48 comments from various entities including the medical device industry, academic medical centers, health care systems, consultants, and medical societies. Regarding centralization of the IDE review process, commenters' opinions were mixed with the majority requesting additional details about the centralized review process, clarification of the IDE study criteria, and delayed implementation of the rule. Commenters expressed concerns about the proposed IDE study criteria, believing that they were duplicative of FDA review activities and suggested that CMS allow for additional input from stakeholders before the rule is finalized. The

following is a summary of the comments we received and our responses.

a. Definitions

<u>Comment</u>: Commenters were concerned that our proposed definition of routine care items and services would limit Medicare coverage of routine care items and services related to Category A or Category B IDE studies. The comments suggested that we align this definition with section 310.1 of the Medicare NCD Manual (Clinical Trials).

Response: We appreciate the commenters' feedback. While we believe that this definition of routine care items and services is aligned with section 310.1 of the Medicare National Coverage Determinations Manual, for purposes of clarity, we are modifying this definition to refer to items and services that are otherwise generally available to Medicare beneficiaries (that is, a benefit category exists, it is not statutorily excluded, and there is no national noncoverage decision) that are furnished during a clinical study and that would be otherwise furnished even if the beneficiary were not enrolled in a clinical study.

b. Provisions for Medicare Coverage of Items and Services in FDA-approved Category A or B IDE studies or trials

Comment: Several commenters were generally supportive of the concept of a centralized Medicare review process for Category A and B IDE studies for purposes of Medicare coverage. However, the commenters requested additional information regarding submission format and review timeframes, with some commenters concerned about the availability of appropriate staff at CMS to complete reviews and issue approvals. Commenters also asked for clarification regarding appeals of Medicare coverage decisions related to Category A or B IDE studies and evaluation/oversight of the CMS Medicare coverage review process.

Response: Seeking Medicare coverage related to Category A or B IDE studies is voluntary. While we are finalizing this rule, we are delaying implementation of these changes

until January 1, 2015. Upon implementation of these changes, interested parties, such as the study sponsor, that wish to seek Medicare coverage in Category A or B IDE studies must submit their requests via email to clinicalstudynotification@cms.hhs.gov or via hard copy to the following address: Centers for Medicare and Medicaid Services; Center for Clinical Standards and Quality; Director, Coverage and Analysis Group; ATTN: Clinical Study Certification; Mail Stop S3-02-01; 7500 Security Blvd.; Baltimore, MD 21244.

Requests must include the following information:

- A request letter that describes the scope and nature of the IDE study, discussing how the interested party believes that the IDE study meets each Medicare Coverage IDE Study
 Criteria.
 - FDA approval letter of the IDE.
 - IDE study protocol.
 - IRB approval letter.
 - National Clinical Trial (NCT) number.
 - Supporting materials, as appropriate.

We understand and appreciate commenters' concerns regarding review time and the availability of appropriate staff to complete the reviews. Once a complete request is received by CMS (or its designated entity), we expect that the review timeframe will be approximately 30 days. While we believe that we have sufficient resources to process Medicare coverage reviews of the IDE studies, we are modifying the provisions of section 405.211 to allow for reviews by a CMS-designated entity if future needs arise.

We anticipate that claims for routine care items and services related to Category A or B

IDE studies and claims for Category B IDE devices will continue to be submitted to local

Medicare contractors who will identify routine costs for which Medicare payment is made for

each related claim. We plan to issue appropriate manual instructions to Medicare contractors. Additional information regarding Medicare claim appeals is available on the CMS website at http://www.cms.gov/Medicare/Appeals-and-Grievances/OrgMedFFSAppeals/index.html.

Comment: A few commenters opposed a centralized Medicare coverage process for Category A or B IDE studies and believed that the current local Medicare contractor review process is sufficient, that centralization could increase approval time, and may not have the intended impact of eliminating inconsistencies in coverage. Several commenters suggested that CMS focus on streamlining claims processing for routine costs incurred by Medicare beneficiaries participating in clinical trials. One commenter was concerned that local Medicare contractors may impose additional coverage requirements.

Response: While some stakeholders may be satisfied with the current localized coverage review process, we believe that centralizing the submission, review and determination of Medicare coverage IDE study requests enhances administrative efficiency by eliminating the need for duplicative submission of requests by providers and duplicative reviews by local Medicare contractors. For example, under existing procedures, each provider that participates in an IDE trial and that anticipates filing Medicare claims must notify the Medicare contractor and furnish the contractor with certain information about the IDE trial. Once the contractor notifies the provider that all required information for the IDE study has been furnished, the provider may bill related Category A or B IDE claims.

Effective January 1, 2015, interested parties (such as study sponsors) that wish to seek Medicare coverage related to Category A or B IDE studies, will have a centralized point of contact for submission, review and determination of Medicare coverage IDE study requests. Providers will no longer need to notify individual contractors regarding IDE studies for which they plan to submit claims since CMS-approved Category A and B IDE studies will be listed on

the CMS website and in the **Federal Register**. We encourage providers to check the CMS website to see if an IDE study has been approved for coverage before submitting IDE related claims.

<u>Comment</u>: Some commenters believed that the Medicare coverage requirements duplicate the responsibilities of the FDA (such as review of scientific and ethical standards) with commenters suggesting that CMS deem coverage for Category A or B IDE studies that have received FDA and IRB approval.

Response: CMS and FDA operate under different statutory authorities and have distinct authorities and responsibilities. FDA approves IDE studies or trials when, among other things, the risks to the subjects are outweighed by the anticipated benefits and the importance of the knowledge to be gained. For purposes of Medicare coverage, we seek evidence that an item or service is reasonable and necessary. The disease burden borne by elderly individuals and the important health care interventions unique to the Medicare population are important areas of focus for the Medicare program; we would not expect the FDA review to include substantive consideration of these Medicare priorities. Thus, we believe that Medicare coverage standards are needed for IDE studies for which Medicare coverage is sought. We wish to ensure that Medicare beneficiaries who volunteer to participate in studies are protected, that the study design is appropriate to answer questions of importance to the Medicare program, and to ensure that the information gained from important clinical trials could be used to inform Medicare coverage decisions.

There are numerous studies that may be considered scientifically valid but are of little benefit to Medicare beneficiaries or to the Medicare program. We believe that this policy establishes Medicare coverage requirements that need to be met to best support a body of clinical knowledge that is relevant to the Medicare program and its beneficiaries. It is essential that IDE

studies where Medicare coverage is sought serve the best interests of the Medicare program and its beneficiaries; and that they be useful in improving healthcare delivery to Medicare beneficiaries, and informing Medicare coverage.

Comment: Commenters suggested that the proposed coverage requirements would increase burden and create access barriers for Medicare coverage of Category A IDE routine care items and services and Category B IDE devices and routine care items and services, particularly in small or localized studies or trials. Commenters suggested that these changes may decelerate medical device innovation and that many sponsors may choose not to seek Medicare coverage for IDE trials due to possible delays during the transition to these new coverage requirements. Other commenters suggested that we pilot a voluntary centralized coverage review process for at least a year, or establish separate review processes for small and large studies since commenters believed that the existing review process by local Medicare contractors is appropriate for small, single-site studies, and that centralized review should only be applied to large, national studies. Some commenters requested clarification regarding whether Medicare would automatically cover items and services related to Category A or B IDE studies, if the studies met the criteria in proposed new \$405.212.

Response: Seeking Medicare coverage related to Category A or B IDE studies is voluntary under existing procedures and will continue to be voluntary under the provisions of this final rule. Study sponsors are not required to seek Medicare coverage in order to conduct their studies or trials. Establishing separate Medicare coverage for IDE study review processes for large and small studies would create unnecessary infrastructure. Similarly, piloting the centralized Medicare coverage IDE study review process would create more duplication and variation in reviews and coverage of items and services, in addition to the variation currently present under the existing local Medicare contractor review process.

In this final rule, we are revising §405.211(a) to specify that Medicare covers routine care items and services that are furnished in FDA-approved Category A IDE studies if CMS (or its designated entity) determines that the IDE study criteria in §405.212 are met. We are also revising §405.211(b) to specify that Medicare may make payment for Category B IDE devices and routine care items and services furnished in FDA-approved Category B IDE studies if CMS (or its designated entity) determines that the IDE study criteria in §405.212 are met.

<u>Comment</u>: One commenter expressed concern that beneficiaries could be at risk of losing Medicare coverage for medical emergencies and other health care items and services that would otherwise be available to Medicare beneficiaries outside of an IDE study or trial.

Response: We do not believe this policy will have an impact on coverage for treatment of an individual trial participant with a medical emergency because this policy does not address Medicare coverage provisions outside the context of a Category A or B IDE study or trial. We would not expect to make a separate review of the IDE study information submitted to CMS (or its designated entity) for each enrolled subject or each related claim submitted to Medicare contractors for adjudication. Additionally, we are unaware of any current paradigm by which an FDA approved IDE trial would be conceived, developed, reviewed and approved in such a short timeframe, that is, a few minutes or hours, to address a beneficiary's medical emergency.

<u>Comment</u>: Commenters requested information about what role, if any, the FDA would serve in the proposed centralized IDE review process for purposes of Medicare coverage of Category A IDE routine care items and services and Category B IDE devices and routine care items and services.

Response: We did not propose any changes to §405.203, which addresses FDA categorization of IDE devices and subsequent FDA notification to CMS regarding such categorization.

c. Medicare Coverage IDE Study Criteria

Comment: Many commenters believed that proposed criterion 1 (the principal purpose of the study is to test whether the item or service meaningfully improves health outcomes in patients who are represented by the Medicare-enrolled subjects), was too specific to the Medicare population and should more closely align with FDA requirements since IDE studies are designed to answer FDA regulatory questions, not Medicare or other insurer coverage questions. Some commenters suggested that we modify the standard to indicate that measuring meaningful outcomes in Medicare beneficiaries need not be the principal purpose, but only one of the purposes.

Response: As discussed in the preamble to the proposed rule, we believe that this criterion is necessary because it embodies important scientific and ethical considerations needed to ensure that the study design is appropriate to answer questions of importance to Medicare and its beneficiaries. We expect that the results of all approved studies will specifically benefit the Medicare population and, as such, covered studies or trials must address how the study will affect Medicare beneficiaries if it desires to receive Medicare payment for services provided to Medicare beneficiaries within that study. However, based on the comments received, we are modifying this criterion to state that the principal purpose of the study is to test whether the device improves health outcomes of appropriately selected patients, since a discussion of the potential benefit of the device being studied to the applicable Medicare population is implicit in other criteria.

<u>Comment</u>: Commenters suggested that we remove or modify the second proposed criterion (the rationale for the study is well supported by available scientific and medical information, or it is intended to clarify or establish the health outcomes of interventions already in common clinical use). Commenters believed that there is already well established government

oversight, and self-governance through IRBs and scientific review committees. The commenters requested additional guidance regarding how this criterion would align with FDA requirements and oversight through the IRBs and scientific committees.

Response: Study protocols typically have a section that describes the scientific rationale for the research. We believe that this criterion reflects a fundamental principle of research and does not require something that would otherwise be absent from a *bona fide* clinical study protocol. We seek assurance of compliance with this criterion because it is needed to ensure that the study or trial focuses on health outcomes important to the Medicare program and its beneficiaries. Therefore, we are not making changes to this criterion.

<u>Comment</u>: Some commenters were concerned about how proposed criterion 3 (the study results are not anticipated to unjustifiably duplicate existing knowledge) would affect IDE device studies that are versions of devices already on the market. A commenter believed that this criterion should not be used to restrict Medicare coverage of IDE studies that build on an existing body of evidence or that provide confirmatory data on new devices.

Response: We realize that FDA reviews many new devices being tested in IDE trials that may be similar to devices already on the market, and that this process is a necessary part of competition and innovation. However, because we are not assured that all devices of a similar class will necessarily have identical benefits and harms, we do not believe, as a general principle, that IDE studies or trials addressing new device versions always duplicate prior knowledge. We expect that knowledge about new devices or significantly changed devices will add to, rather than duplicate, existing knowledge. We believe this criterion is necessary to ensure that the study focuses on health outcomes important to the Medicare program and its beneficiaries. Therefore, we are not making changes to this criterion.

<u>Commenters</u>: Commenters stated that proposed criterion 4 (the study design is

methodologically appropriate and the anticipated number of enrolled subjects is adequate to answer the research question(s) being asked in the study) is duplicative of the FDA's role. One commenter asked how we would determine if a study design is methodologically appropriate.

Response: Fundamentally, bona fide clinical research depends on the use of study designs that are appropriate to address the study questions. Otherwise there is no real production of generalizable knowledge, which is the hallmark of research, and enrolled subjects encounter risk without a realistic expectation that their participation will result in personal or societal benefit relevant to the Medicare program. The use of such a device in an IDE study may expose the study participants to increased risks that must be balanced by other factors including the likelihood that the study would add important information to the body of medical knowledge relevant to the Medicare program. There are numerous studies that may be considered scientifically valid but are of little benefit to the Medicare program. We are sensitive to the unique needs of Medicare beneficiaries, particularly the elderly. A trial design that may be adequate for a generally younger population may be comparatively insensitive to clinical factors commonly found in the elderly that may adversely impact the potential benefit or tolerability of a device, which is of particular importance to the Medicare program.

<u>Comment</u>: A few commenters requested information on how proposed criterion 5 (the study is sponsored by an organization or individual capable of completing it successfully) will be used to determine that the sponsoring organization or individual is capable of completing a study successfully.

Response: Institutional capabilities and scientific expertise are typically described in study protocols, which will be reviewed by CMS. Robust clinical studies depend on a supporting infrastructure to assure protocol adherence and that intended patient protections are actually in place. Clinical trials that are not completed successfully expose enrolled subjects to

the risks of research participation without the benefit of producing generalizable knowledge applicable to the Medicare program. We believe that this criterion reflects a fundamental principle of research and does not require something that would otherwise be absent from a bona fide clinical study protocol. Therefore, we are finalizing this criterion as proposed.

<u>Comment</u>: One commenter suggested that for proposed criterion 6 (the study is in compliance with all applicable Federal regulations concerning the protection of human subjects found at 45 CFR part 46) that we also require compliance with FDA regulations at 21 CFR 50 (Informed Consent) and 21 CFR 56 (Institutional Review Board oversight) since 45 CFR 46 only refers to government funded research.

Response: We agree with the commenter's suggestions and are modifying this criterion in this final rule to require that the study is in compliance with all applicable Federal regulations concerning the protection of human subjects found at 21 CFR parts 50, 56, and 812, and 45 CFR part 46.

<u>Comment:</u> Commenters recommended that we delete the reference to the International Committee of Medical Journal Editors in proposed criterion 7 (all aspects of the study are conducted according to appropriate standards of scientific integrity set by the International Committee of Medical Journal Editors.

Response: In response to the comments received, we are removing proposed criterion 7. We believe that the intent of proposed criterion 7 can be largely accomplished by adherence to the remaining CMS IDE study criteria.

We are also removing proposed criterion 8 (the study has a written protocol that clearly demonstrates adherence to the standards listed here as Medicare requirements) because the intent of proposed criterion 8 is implicit in the CMS coverage criteria and requirements.

Comment: One commenter suggested that proposed criterion 9 (where appropriate, the

clinical research study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Trials of all medical technologies measuring therapeutic outcomes as one of the objectives may be exempt from this standard only if the disease or condition being studied is life threatening and the patient has no other viable treatment options), since the commenter believed that Medicare would only be furnishing coverage for "conventional" care.

Response: As discussed in the preamble to the proposed rule, the intent of this criterion is to limit Medicare coverage to IDE studies that do not exclusively test toxicity or disease pathophysiology in healthy individuals, but also have a therapeutic outcome. However, a study that exclusively tests toxicity or disease pathophysiology may still be covered if the disease or condition being studied is life-threatening or a severely-debilitating illness, and the patient has no other viable treatment options. We recognize that many research projects could be considered to have varying degrees of contributions towards understanding interventions that improve health outcomes for the Medicare program. While we agree that in some cases, safety and toxicity studies may assess the benefits of the interventions they examine, and in limited circumstances may be considered appropriate to inform the clinical knowledge base applicable to the Medicare program, we are maintaining this criterion without change.

Comment: Commenters expressed interest in the possible impact of the rule on ClinicalTrials.gov reporting, and suggested that we require that proposed criterion 10 (the study is registered on the ClinicalTrials.gov website and/or the Registry of Patient Registries (RoPR) by the principal sponsor/investigator prior to the enrollment of the first study subject) comply with section 801 of the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Pub. L. 110-85, enacted on September 27, 2007), which requires registration on ClinicalTrials.gov within 21 days of enrollment of the first subject.

Response: As discussed in the preamble to the proposed rule, we believe that all studies

seeking Medicare coverage under this policy should be registered with ClinicalTrials.gov. Registrants at ClinicalTrials.gov must submit a standardized set of data elements to describe the study design, eligible populations, outcome measures, and other parameters and results. Registration, for some studies, serves as a vehicle for Medicare beneficiaries to learn about, and identify studies in which they may want to participate. When results reporting is required, it also offers an assurance of quality because, generally, public access to information enables a higher level of accountability in the accurate reporting of the clinical study protocol and results, and in the conduct of the trial itself. This accountability derives both from public access to information about studies and from the risk of penalty for submitting false or misleading clinical trial information. We recognize that, for some studies of unapproved devices, FDAAA prohibits the public display of information on registration and results until after the device is approved or cleared for marketing. We have revised our regulation to avoid indicating that Medicare coverage of such IDE studies would require public display of all information in Clinical Trials gov for these unapproved devices. However, we believe that delayed display for this subset of studies, should the device be cleared or approved for marketing, will not significantly undermine our goals. For some studies, we expect public access to ClinicalTrials.gov data will not be delayed and therefore our requirement will immediately lead to greater public transparency for many of the studies supported by Medicare. For those studies about which information cannot be displayed publicly prior to marketing approval, we believe that the possibility of future public access and the risk of liability for the submission of false or misleading clinical trial information to Clinical Trials gov remain valuable. Registration with ClinicalTrials.gov also assures that Medicare beneficiaries and their treating healthcare professionals will, for those devices ultimately approved or cleared by FDA, eventually have pertinent information about these IDE studies. We note that clinical trials of devices that register

for purposes of this regulation are subject to any applicable requirements under FDAAA. Finally, we have modified the criteria to simply require registration on ClinicalTrials.gov.

<u>Comment</u>: In summary, proposed criterion 11 stated that the study protocol must specify the method and timing of public release of results on all pre-specified outcomes, including release of negative outcomes. One commenter stated that time to publication may not be in the control of the sponsors and that some studies may not be published at all for various reasons. Commenters suggested that we modify this criterion to be consistent with section 801 of the FDAAA.

Response: Based on the comments received, we are modifying this criterion to state that the study protocol describes the method and timing of release of results on all pre-specified outcomes, including release of negative outcomes and that the release should be hastened if the study is terminated early.

Comment: In summary, proposed criteria 12 and 13 stated that the study protocol must explicitly discuss the subpopulations affected by the items or services under investigation and discuss how the study results would be expected to be generalizable to the Medicare population. Commenters believed that explicitly requiring this information in the study protocol was inappropriate, with other commenters indicating that this information could be provided in the request for coverage submission package versus explicitly requiring it in the study protocol. A commenter stated that generalizability to populations beyond those which are studied in the trial may be difficult to articulate, especially when the class of device is new. Commenters opined that if the device class is the subject of a Medicare national or local coverage decision, the criterion is redundant and may create undue burden on a trial being conducted in a least burdensome environment.

One commenter suggested that for devices that represent a device improvement, the

existing body of knowledge and other supporting documents will likely address sub- and special populations. The commenter also stated that for truly new devices, safety and efficacy at a baseline level are not yet established and that a mandate to include special populations and under-represented groups is likely to be prohibitive to completion of the trial.

Response: We want to support and encourage the conduct of research studies that add to the knowledge base about efficient, appropriate, and effective use of products and technologies in the Medicare population, thus improving the quality of care that Medicare beneficiaries receive. We understand the commenters' concerns; however, we expect that the results of studies or trials approved for purposes of Medicare coverage will specifically benefit the Medicare population.

It is not our intention to require enrollment of all subpopulations. It is, however, our intention that study protocols for which Medicare coverage is sought address all populations affected by the technology under investigation, specifically those of interest to the Medicare program (populations due to age, disability, or other eligibility status). We expect that protocols describe the potential for subgroup differences and discuss how the study will evaluate any differences found.

In this final rule, we are combining and modifying proposed criteria 11 and 12 to state that for purposes of Medicare coverage, Category A or Category B IDE study protocols must discuss how Medicare beneficiaries may be affected by the device under investigation, how the study results are or are not expected to be generalizable to the Medicare population, and must include separate discussions for populations eligible for Medicare due to age, disability, or other eligibility status.

<u>Comment</u>: Commenters suggested that we remove the proposed Medicare coverage requirements that a Category A or B IDE study must be a pivotal study and have a superiority

study design. Commenters expressed concern that noninferiority studies were not specifically discussed. One commenter recommended that IDE studies conducted as part of the FDA premarket approval (PMA) process be deemed as meeting the pivotal trial definition and be eligible for automatic coverage. Commenters stated that noninferiority studies and studies without an active comparator are designed to address important research questions and ultimately improve patient care, and cited the following concerns about including this requirement:

- Requiring that the study be either a superiority or pivotal study may undermine innovation.
 - Not all clinical questions require superiority designs.
- Development of devices that are similar to devices already on the market may only require evidence of equivalence or noninferiority to a preexisting device while offering an expanded treatment option and lower healthcare costs through competition in the market.
- Medical device development may follow less well-defined paths of clinical study with individual studies not always easily characterized by a specific Phase, but still providing important evidence on a device's safety and effectiveness.
- In many cases, the protocol is not changed between the pilot and pivotal phases and including this requirement may make studies in the pilot phase ineligible for coverage.
- Investigator-initiated studies often evaluate novel approaches in small studies and are unlikely to be pivotal.

Response: We appreciate the commenters' concerns about the proposed pivotal study and superiority study design Medicare coverage criteria. We believe that noninferiority trial designs are recognized to have certain risks of bias that are mitigated in superiority trial designs. These criteria were intended as specific positive factors that could have streamlined the Medicare coverage review of IDE study protocols. We did not intend that these proposals would be

absolute requirements or that IDE studies that are not pivotal or studies with noninferiority designs could not be approved for Medicare coverage. Therefore, we are modifying the Medicare coverage IDE study criteria in new §405.212 by removing the proposed pivotal study and superiority study design coverage requirements and removing the proposed definitions of pivotal studies or trials and superiority studies or trials in revised §405.201(b).

d. Additional issues

<u>Comment</u>: Commenters stated that submitting IRB letters for every site involved in a multi-site clinical trial would create significant burden for stakeholders and is duplicative of the FDA's review process.

Response: We believe that Medicare beneficiaries should be enrolled in studies that have been vetted by IRBs. However, we recognize commenters' concerns regarding the potential burden of submitting IRB letters for every site involved in a multi-site clinical trial. Therefore, we are clarifying in this final rule that interested parties, such as the study sponsor, that wish to seek Medicare coverage related to Category A or B IDE studies need only submit one IRB approval letter with their request.

<u>Comment:</u> Commenters requested assurance that information provided by the study sponsor will be kept confidential.

Response: Seeking Medicare coverage for Category A or B IDE trials is voluntary.

Medicare coverage is not a requirement for study sponsors to conduct research. Effective

January 1, 2015, interested parties (such as the study sponsor) that wish to seek Medicare

coverage in Category A or B IDE studies must submit a request to CMS for review and approval

of a Category A or B IDE study in order to meet the Medicare coverage requirements for

Category A or B IDE routine care items and services, and Category B devices.

Upon CMS approval of a Category A or B IDE study, we will post on the CMS website

and periodically in the **Federal Register** limited information supplied by the interested party as part of their Medicare coverage IDE study review request (study title, sponsor name, NCT number, and the IDE number), along with the CMS approval date. We note that the same type of information is currently posted on the CMS website for other clinical study approvals related to Medicare coverage under the coverage with evidence development (CED) paradigm. We note that we did not propose any changes to §405.215, which addresses confidential commercial and trade secret information by specifying that, to the extent that we rely on confidential commercial or trade secret information in any judicial proceeding, we will maintain confidentiality of the of the information in accordance with Federal law.

<u>Comment</u>: Commenters requested information about appropriate procedures for notification of trial revisions, protocol changes, and review of consent forms. One commenter requested that we align with the ClinicalTrials.gov registry, so that sponsors and researchers can provide updates to both systems. Other commenters suggested that instead of notifying the public of CMS-approved IDE studies in the **Federal Register**, that we post this information to the CMS website.

Response: We do not believe that the creation of a shared registry with the National Library of Medicine's ClinicalTrials.gov registry to include information regarding CMS approval of Category A or B IDE studies could be accomplished before the effective date of this regulation. As previously discussed, limited information regarding CMS-approved Category A and B IDE studies will be posted on the CMS website and in the **Federal Register**.

<u>Comment</u>: A few commenters asked how the proposed changes to the coverage requirements would impact or interact with the NCD process, including CED.

Response: Medicare coverage of Category A IDE routine care items and services, and Medicare coverage of Category B IDE devices and routine care items and services do not predict

nor directly lead to Medicare coverage outside of the context of an IDE study, nor does it necessarily lead to consideration under the Medicare national coverage determination (NCD) process. The NCD process is separate and distinct with its own statutory basis and requirements. Additional information regarding the Medicare national coverage determination process can be found on the CMS coverage website at http://www.cms.gov/Center/Special-Topic/Medicare-Coverage-Center.html?redirect=/center/coverage.asp.

<u>Comment</u>: Commenters requested clarification about Medicare coverage of Category A IDE related routine care items and services and Category B IDE devices and related routine care items and services, when the Medicare beneficiary is enrolled in a Medicare Advantage plan or Medicare health plan.

Response: Medicare Advantage plans must abide by the IDE study payment policy as instructed in the Medicare Managed Care Manual, Chapter 4, Section 10.7.2.

4. Summary of Changes to Proposed Provisions

As a result of the comments received, we are making the following changes in this final rule.

- For the purpose of clarity, we are modifying the following definitions to state:
- ++ <u>Category B (Nonexperimental/investigational) device</u> refers to a device for which the incremental risk is the primary risk in question (that is, initial questions of safety and effectiveness of that device type have been resolved), or it is known that the device type can be safe and effective because, for example, other manufacturers have obtaind FDA premarket approval or clearance for that device type.
- ++ Routine care items and services refers to items and services that are otherwise generally available to Medicare beneficiaries (that is, a beneficiary category exists, it is not statutorily excluded, and there is no national noncoverage decision) that are furnished during a clinical study and that would be otherwise furnished even if the beneficiary were not enrolled in

a clinical study.

• We are revising §405.207(b)(3) to state "Routine care items and services related to Category A (Experimental) devices as defined in §405.211."

- We are revising §405.207(b)(3) to state "Routine care items and services related to Category B (Nonexperimental/investigational) devices as defined in §405.201(b), and furnished in conjunction with FDA-approved clinical studies that meet the coverage requirements in §405.211."
 - We are modifying §405.211 so that—
- ++ Medicare covers routine care items and services furnished in an FDA-approved

 Category A IDE study if CMS (or its designated entity) determines that the Medicare coverage

 IDE study criteria in §405.212 are met.
- ++ Medicare may make payment for a Category B (Nonexperimental/investigational)

 IDE device and routine care items and services furnished in an FDA-approved Category B

 (Nonexperimental/investigational) IDE study if CMS (or its designated entity) determines that the Medicare coverage IDE study criteria in §405.212 are met.
- ++ CMS (or its designated entity) must review the following to determine if the Medicare coverage IDE study criteria in §405.212 are met (that is, FDA approval letter of the IDE, IDE study protocol, IRB approval letter, NCT number, and supporting materials, if needed).
- ++ A listing of all CMS-approved Category A IDE studies and Category B IDE studies shall be posted on the CMS website and published in the **Federal Register.**
- We modified new §405.212 (IDE study criteria) to require that, for Medicare coverage of items and services described in §405.211, a Category A (Experimental) or Category B (Nonexperimental/investigational) IDE study must meet all of the following criteria.

++ The principal purpose of the study is to test whether the device improves health outcomes of appropriately selected patients.

- ++ The rationale for the study is well supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use.
 - ++ The study results are not anticipated to unjustifiably duplicate existing knowledge.
- ++ The study design is methodologically appropriate and the anticipated number of enrolled subjects is adequate to confidently answer the research question(s) being asked in the study.
- ++ The study is sponsored by an organization or individual capable of successfully completing the study.
- ++ The study is in compliance with all applicable Federal regulations concerning the protection of human subjects found at 21 CFR parts 50, 56, and 812, and 45 CFR part 46.
- ++ Where appropriate, the study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Studies of all medical technologies measuring therapeutic outcomes as one of the objectives may be exempt from this criterion only if the disease or condition being studied is life threatening and the patient has no other viable treatment options.
- ++ The study is registered with the National Institutes of Health's National Library of Medicine's ClinicalTrials.gov.
- ++ The study protocol describes the method and timing of release of results on all prespecified outcomes, including release of negative outcomes and that the release should be hastened if the study is terminated early.
 - ++ The study protocol must describe how Medicare beneficiaries may be affected by the

device under investigation, and how the study results are or are not expected to be generalizable to the Medicare beneficiary population. Generalizability to populations eligible for Medicare due to age, disability, or other eligibility status must be explicitly described.

We are also making the following conforming changes to 42 CFR 405 subpart B.

- To reflect changes in §405.201(b), we are making conforming changes to the following sections: §405.201(a)(2); §405.203(a)(1) and (a)(2); §405.203(b); §405.205(a)(1); §405.209; §405.213(a)(1); and §411.15(o)(1), by replacing the term experimental/investigational (Category A) device with Category A (Experimental) device, and the term Non-experimental/investigational (Category B) device with Category B (Nonexperimental/investigational) device, as applicable.
- In §405.201(b), we are changing the term IDE to investigational device exemption (IDE) for clarity purposes.
- In §405.207(b)(2), we are making conforming changes to reflect changes to the definitions in §405.201(b) and revised §405.211.
 - In §411.15(o)(2), we are making conforming changes to reflect revised §405.211.

B. Ultrasound Screening for Abdominal Aortic Aneurysms

1. Background and Statutory Authority

Section 1861(s)(2)(AA) of the Act authorizes Medicare coverage under Part B of ultrasound screening for abdominal aortic aneurysms ("AAA screening"), as defined in section 1861(bbb) of the Act. Our implementing regulations for AAA screening are at §410.19. AAA screening is covered for a beneficiary that meets certain criteria including that he or she must receive a referral during the initial preventive physical examination (IPPE) and has not previously had an AAA screening covered under the Medicare program. The IPPE, as described in section 1861(ww) of the Act (and regulations at §410.16), includes a time restriction and must be furnished not more than 1 year after the effective date of the beneficiary's first Part B coverage period (see section 1862(a)(1)(K) of the Act). This time limitation for the IPPE effectively reduces a Medicare beneficiary's ability to obtain a referral for AAA screening.

Section 1834(n) of the Act, added by section 4105 of the Affordable Care Act, grants the Secretary the discretion and authority to modify coverage of certain preventive services identified in section 1861(ddd)(3) of the Act, which in turn cross-references section 1861(ww)(2) of the Act (including AAA screening at section 1861(ww)(2)(L)). The Secretary may modify coverage to the extent that such modification is consistent with the recommendations of the United States Preventive Services Task Force (USPSTF) per section 1834(n)(1)(A) of the Act. In 2005, the USPSTF recommended "one-time screening for [AAA] by ultrasonography in men aged 65 through 75 who have ever smoked. (Grade: B Recommendation)" (Screening for Abdominal Aortic Aneurysm: Recommendation Statement.

http://www.uspreventiveservicestaskforce.org/uspstf05/aaascr/aaars.htm). The USPSTF recommendation does not include a time limit with respect to the referral for this test.

2. Provisions of the Regulations for Final Rule with Comment Period

We proposed to exercise our discretion and authority under section 1834(n) of the Act to modify coverage of AAA screening consistent with the recommendations of the USPSTF to eliminate the one-year time limit with respect to the referral for this service. This modification will allow coverage of AAA screening for eligible beneficiaries without requiring them to receive a referral as part of the IPPE.

Specifically for purposes of coverage of AAA screening, we proposed to modify the definition of "eligible beneficiary" in §410.19(a) by removing paragraph (1) of the definition of "eligible beneficiary" and redesignating paragraphs (2) and (3) of the definition of "eligible beneficiary" as paragraphs (1) and (2), respectively.

The IPPE is a one-time benefit available to beneficiaries under Part B that receive the IPPE not more than 1 year after the effective date of the beneficiary's first Medicare Part B coverage period. Many beneficiaries were either not eligible to receive an IPPE (which did not become effective until January 1, 2005) or may not have taken advantage of the IPPE when they were eligible, which limited beneficiary access to coverage of AAA screening. We believe that our modification is consistent with current USPSTF recommendations for one-time screening and allows for expanded access to this important preventive service.

We received 12 public comments from various entities including physician specialty societies, a manufacturer and a manufacturer advocacy group, a beneficiary advocacy organization, a medical group management association, and a health insurer. All of the comments supported our proposal to modify coverage of AAA screening to eliminate the one-year time limit with respect to the referral for this service. Below is a summary of comments received and our response.

<u>Comment</u>: Two commenters believed that the proposed modification to eliminate the one-year time limit with respect to the referral for AAA screening would only apply to men aged 65-75 who are smokers, and that individuals with a family history would continue to be required to receive a referral from the IPPE in order to be eligible for coverage of AAA screening.

Response: This modification eliminates the one-year time limit with respect to referral for this service and allows coverage of AAA screening for all beneficiaries that meet the eligibility requirements for this benefit without requiring them to receive a referral as part of the IPPE. An eligible beneficiary, for purposes of this covered service, is an individual that meets the following criteria:

Has not been previously furnished AAA screening under the Medicare program; and

• Is included in at least one of the following risk categories: (1) has a family history of an abdominal aortic aneurysm; or (2) is a man aged 65 to 75 who has smoked at least 100 cigarettes in his lifetime.

After taking into consideration the public comments received, we are finalizing this policy as proposed.

C. Colorectal Cancer Screening: Modification to Coverage of Screening Fecal Occult Blood Tests

1. Background and Statutory Authority

Sections 1861(s)(2)(R) and 1861(pp)(1) of the Act authorize Medicare coverage of colorectal cancer screening. The statute authorizes coverage of screening fecal occult blood tests (FOBT), screening flexible sigmoidoscopies, screening colonoscopies, and other tests determined to be appropriate, subject to certain frequency and payment limits. Our implementing regulations are codified at §410.37. Section 410.37(b) (condition for coverage of screening FOBT) specifies that Medicare Part B pays for screening FOBT if ordered in writing by the beneficiary's attending physician. For purposes of §410.37, "attending physician" is defined as "a doctor of medicine or osteopathy (as defined in section 1861(r)(1) of the Act) who is fully knowledgeable about the beneficiary's medical condition, and who would be responsible using the results of any examination performed in the overall management of the beneficiary's specific medical problem."

The coverage provisions for FOBT screening were established in 1997 and effective on January 1, 1998 (62 FR 59048, October 31, 1997). In the preamble to that final rule, we stated that the requirement for a written order from the attending physician was intended to make certain that beneficiaries receive appropriate preventive counseling about the implications and possible results of having these examinations performed (62 FR 59081).

Since then, Medicare coverage of preventive services has expanded to include, among other things, coverage of an annual wellness visit (as defined in §410.15). The annual wellness visit includes provisions for furnishing personalized health advice and appropriate referrals. In addition to physicians,

the annual wellness visit can be furnished by certain nonphysician practitioners, including physician assistants, nurse practitioners, and clinical nurse specialists.

We also note that §410.32, which provides coverage and payment rules for diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests, states in subsection (a)(2): "Nonphysician practitioners (that is, clinical nurse specialists, clinical psychologists, clinical social workers, nurse-midwives, nurse practitioners, and physician assistants) who furnish services that would be physician services if furnished by a physician, and who are operating within the scope of their authority under State law and within the scope of their Medicare statutory benefit, may be treated the same as physicians treating beneficiaries for the purpose of this paragraph."

2. Provisions of the Regulations for Final Rule with Comment Period

We proposed to revise §410.37(b), "Condition for coverage of screening fecal-occult blood tests," to allow an attending physician, physician assistant, nurse practitioner, or clinical nurse specialist to furnish written orders for screening FOBT. These modifications will allow for expanded coverage and access to screening FOBT, particularly in rural areas.

We received 8 public comments from various entities including physician and practitioner specialty societies, a pharmaceutical manufacturer, a beneficiary advocacy organization, a medical center, and a health insurer. All of the commenters supported our proposal to expand the types of practitioners that are able to furnish written orders for screening FOBT, in addition to a beneficiary's attending physician. Additionally, we invited public comment regarding whether a practitioner permitted to order a screening FOBT must be the beneficiary's attending practitioner as described earlier. Below is a summary of the comments received and our response.

<u>Comment</u>: One commenter suggested that the practitioners ordering the test function under the direct and responsible supervision of a practicing, licensed physician. Another commenter thought that the qualified practitioner furnishing the order should be knowledgeable about the patient and their plan of care. One commenter opined that the limitation of orders from the attending practitioner should be removed to prevent unnecessary office visits with the patient, scheduled solely to demonstrate compliance

with a requirement that the test results be used in the practitioner's management of the patient's condition.

The same commenter suggested that decisions regarding the medical necessity of follow-up care be left to the clinical judgment of the practitioner.

Response: After considering the public comments, we are retaining the "attending" requirement that provides assurance that the non-physician practitioner will be knowledgeable about the patient and the patient's plan of care. We are not requiring that these practitioners act only under the direct supervision of a practicing licensed physician as we view this suggestion as contrary to our goal of increasing access to this screening test, particularly in rural areas. Our expansion of coverage of screening FOBT to include tests ordered by an attending physician assistant, nurse practitioner, or clinical nurse specialist are consistent with the requirements for tests ordered for diagnostic purposes where nonphysician practitioners may be treated the same as physicians treating beneficiaries. The attending practitioner (physician, physician assistant, nurse practitioner, or clinical nurse specialist) would be responsible for using the results of the screening test in the overall management of the beneficiary's medical care. We leave it to the discretion of the attending practitioner to determine what follow-up care may be necessary. After consideration of the public comments received, we are implementing this policy as proposed.

D. Ambulance Fee Schedule

1. Amendment to Section 1834(1)(13) of the Act

Section 146(a) of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110-275, enacted on July 15, 2008) (MIPPA) amended section 1834(l)(13)(A) of the Act to specify that, effective for ground ambulance services furnished on or after July 1, 2008 and before January 1, 2010, the ambulance fee schedule amounts for ground ambulance services shall be increased as follows:

- For covered ground ambulance transports that originate in a rural area or in a rural census tract of a metropolitan statistical area, the fee schedule amounts shall be increased by 3 percent.
- For covered ground ambulance transports that do not originate in a rural area or in a rural census tract of a metropolitan statistical area, the fee schedule amounts shall be increased by 2 percent.

Sections 3105(a) and 10311(a) of the Affordable Care Act further amended section 1834(l)(13)(A) of the Act to extend the payment add-ons described above for an additional year, such that these add-ons also applied to covered ground ambulance transports furnished on or after January 1, 2010, and before January 1, 2011. In the CY 2011 PFS final rule with comment period (75 FR 73385, 73386, 73625), we revised §414.610(c)(1)(ii) to conform the regulations to this statutory requirement.

Section 106(a) of the Medicare and Medicaid Extenders Act of 2010 (Pub. L.111-309, enacted December 15, 2010) (MMEA) again amended section 1834(1)(13)(A) of the Act to extend the payment add-ons described above for an additional year, such that these add-ons also applied to covered ground ambulance transports furnished on or after January 1, 2011, and before January 1, 2012. In the CY 2012 End-Stage Renal Disease Prospective Payment System (ESRD PPS) final rule (76 FR 70228, 70284 through 70285, and 70315), we revised §414.610(c)(1)(ii) to conform the regulations to this statutory requirement.

Section 306(a) of the Temporary Payroll Tax Cut Continuation Act of 2011 (TPTCA) (Pub. L. 112-78, enacted on December 23, 2011) amended section 1834(l)(13)(A) of the Act to extend the payment add-ons described above through February 29, 2012; and section 3007(a) of the Middle Class Tax Relief and Job Creation Act of 2012 (Pub. L. 112-96, enacted on February 22, 2012) (MCTRJCA)

further amended section 1834(1)(13)(A) of the Act to extend these payment add-ons through December 31, 2012. Thus, these payment add-ons also applied to covered ground ambulance transports furnished on or after January 1, 2012 and before January 1, 2013. In the CY 2013 PFS final rule (77 FR 69139, 69368), we revised §414.610(c)(1)(ii) to conform the regulations to this statutory requirement.

Subsequently, section 604(a) of the ATRA amended section 1834(l)(13)(A) of the Act to extend the payment add-ons described above through December 31, 2013. Thus, these payment add-ons also apply to covered ground ambulance transports furnished on or after January 1, 2013 and before January 1, 2014. In the proposed rule, we proposed to revise §414.610(c)(1)(ii) to conform the regulations to this statutory requirement. We did not receive any comments on this proposal. Accordingly, we are finalizing our proposal to revise §414.610(c)(1)(ii) to conform the regulations to the statutory requirement described above.

This statutory requirement is self-implementing. A plain reading of the statute requires only a ministerial application of the mandated rate increase, and does not require any substantive exercise of discretion on the part of the Secretary.

2. Amendment to Section 146(b)(1) of MIPPA

Section 146(b)(1) of MIPPA amended the designation of certain rural areas for payment of air ambulance services. This section originally specified that any area that was designated as a rural area for purposes of making payments under the ambulance fee schedule for air ambulance services furnished on December 31, 2006, must continue to be treated as a rural area for purposes of making payments under the ambulance fee schedule for air ambulance services furnished during the period July 1, 2008 through December 31, 2009.

Sections 3105(b) and 10311(b) of the Affordable Care Act amended section 146(b)(1) of MIPPA to extend this provision for an additional year, through December 31, 2010. In the CY 2011 PFS final rule (75 FR 73385, 73386, and 73625 through 73626), we revised §414.610(h) to conform the regulations to this statutory requirement.

Section 106(b) of the MMEA amended section 146(b)(1) of MIPPA to extend this provision again through December 31, 2011. In the CY 2012 ESRD PPS final rule (76 FR 70284, 70285, and 70315), we revised §414.610(h) to conform the regulations to this statutory requirement.

Subsequently, section 306(b) of the TPTCCA amended section 146(b)(1) of MIPPA to extend this provision through February 29, 2012; and section 3007(b) of the MCTRJCA further amended section 146(b)(1) of MIPPA to extend this provision through December 31, 2012. In the CY 2013 PFS final rule (77 FR 69139, 69140, and 69368), we revised §414.610(h) to conform the regulations to this statutory requirement.

Subsequently, section 604(b) of the ATRA amended section 146(b)(1) of MIPPA to extend this provision through June 30, 2013. Thus, we proposed to revise §414.610(h) to conform the regulations to this statutory requirement. We did not receive any comments on this proposal. Therefore, we are finalizing our proposal to revise §414.610(h) to conform the regulations to the statutory requirement described above.

This statutory requirement is self-implementing. A plain reading of the statute requires only a ministerial application of a rural indicator, and does not require any substantive exercise of discretion on the part of the Secretary. Accordingly, for areas that were designated as rural on December 31, 2006, and were subsequently re-designated as urban, we re-established the "rural" indicator on the ZIP Code file for air ambulance services through June 30, 2013.

3. Amendment to Section 1834(1)(12) of the Act

Section 414 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (Pub. L. 108-173, enacted on December 8, 2003) (MMA) added section 1834(I)(12) to the Act, which specified that in the case of ground ambulance services furnished on or after July 1, 2004, and before January 1, 2010, for which transportation originates in a qualified rural area (as described in the statute), the Secretary shall provide for a percent increase in the base rate of the fee schedule for such transports. The statute requires this percent increase to be based on the Secretary's estimate of the average cost per trip for such services (not taking into account mileage) in the lowest quartile of all rural county

populations as compared to the average cost per trip for such services (not taking into account mileage) in the highest quartile of rural county populations. Using the methodology specified in the July 1, 2004 interim final rule (69 FR 40288), we determined that this percent increase was equal to 22.6 percent. As required by the MMA, this payment increase was applied to ground ambulance transports that originated in a "qualified rural area"; that is, to transports that originated in a rural area included in those areas comprising the lowest 25th percentile of all rural populations arrayed by population density. For this purpose, rural areas included Goldsmith areas (a type of rural census tract).

Sections 3105(c) and 10311(c) of the Affordable Care Act amended section 1834(l)(12)(A) of the Act to extend this rural bonus for an additional year through December 31, 2010. In the CY 2011 PFS final rule with comment period (75 FR 73385, 73386 and 73625), we revised §414.610(c)(5)(ii) to conform the regulations to this statutory requirement.

Section 106(c) of the MMEA amended section 1834(1)(12)(A) of the Act to extend the rural bonus described above for an additional year, through December 31, 2011. Therefore, in the CY 2012 ESRD PPS final rule (76 FR 70284, 70285 and 70315), we revised §414.610(c)(5)(ii) to conform the regulations to this statutory requirement.

Section 306(c) of the TPTCCA amended section 1834(l)(12)(A) of the Act to extend this rural bonus through February 29, 2012; and section 3007(c) of the MCTRJCA further amended section 1834(l)(12)(A) of the Act to extend this rural bonus through December 31, 2012. In the CY 2013 PFS final rule with comment period (77 FR 69140, 69368), we revised §414.610(c)(5)(ii) to conform the regulations to these statutory requirements.

Subsequently, section 604(c) of the ATRA amended section 1834(l)(12)(A) of the Act to extend this rural bonus through December 31, 2013. Therefore, we are continuing to apply the 22.6 percent rural bonus described above (in the same manner as in previous years), to ground ambulance services with dates of service on or after January 1, 2013 and before January 1, 2014 where transportation originates in a qualified rural area.

This rural bonus is sometimes referred to as the "Super Rural Bonus" and the qualified rural areas (also known as "super rural" areas) are identified during the claims adjudicative process via the use of a data field included on the CMS-supplied ZIP Code File.

In the proposed rule, we proposed to revise §414.610(c)(5)(ii) to conform the regulations to the statutory requirement set forth at section 604(c) of the ATRA. We did not receive any comments on this proposal. Accordingly, we are finalizing our proposal to revise §414.610(c)(5)(ii) to conform the regulations to this statutory requirement.

This statutory requirement is self-implementing. This provision requires a one-year extension of the rural bonus (which was previously established by the Secretary) through December 31, 2013, and does not require any substantive exercise of discretion on the part of the Secretary.

4. Addition of section 1834(1)(15) of the Act

Section 637 of the ATRA, which added section 1834(I)(15) of the Act, specifies that the fee schedule amount otherwise applicable under the preceding provisions of section 1834(I) of the Act shall be reduced by 10 percent for ambulance services furnished on or after October 1, 2013, consisting of non-emergency basic life support (BLS) services involving transport of an individual with end-stage renal disease for renal dialysis services (as described in section 1881(b)(14)(B) of the Act) furnished other than on an emergency basis by a provider of services or a renal dialysis facility. We proposed to revise §414.610 by adding paragraph (c)(8) to conform the regulations to this statutory requirement. We did not receive any comments on this proposal. Accordingly, we are finalizing our proposal to revise §414.610 by adding paragraph (c)(8) to conform the regulations to the statutory requirement described above.

This statutory requirement is self-implementing. A plain reading of the statute requires only a ministerial application of the mandated rate decrease, and does not require any substantive exercise of discretion on the part of the Secretary. Accordingly, for the ambulance services described in section 637 of the ATRA furnished on or after October 1, 2013, the fee schedule amount otherwise applicable (both base rate and mileage) is reduced by 10 percent. For further information regarding application of this mandated rate decrease, please see CR 8269.

5. Studies of Ambulance Costs

Section 604(d)(1) of the ATRA provides that the Secretary shall conduct the following studies:

- (A) A study that analyzes data on existing cost reports for ambulance services furnished by hospitals and critical access hospitals, including variation by characteristics of such providers of services, with a Report to Congress on such study due by October 1, 2013; and
- (B) A study of the feasibility of obtaining cost data on a periodic basis from all ambulance providers of services and suppliers for potential use in examining the appropriateness of the Medicare add-on payments for ground ambulance services furnished under the fee schedule under section 1834(1) of the Act and in preparing for future reform of such payment system, with a Report to Congress due on such study by July 1, 2014.

Further, in conducting the study under paragraph (B) above, section 604(d)(2) of the ATRA directs the Secretary to:

- Consult with industry on the design of such cost collection efforts;
- Explore the use of cost surveys and cost reports to collect appropriate cost data and the periodicity of such cost data collection;
- Examine the feasibility of developing a standard cost reporting tool for providers of services and suppliers of ground ambulance services; and
- Examine the ability to furnish such cost data by various types of ambulance providers of services and suppliers, especially by rural and super-rural providers of services and suppliers.

As noted above, in conducting the study under section 604(d)(1) of the ATRA described in paragraph (B) above, the Secretary is required to consult with industry on the design of such cost collection efforts (see section 604(d)(2)(A) of the ATRA). We used the proposed rule as the instrument to collect information, comments, and ideas from the industry on the design of such cost collection efforts as described above, and on the feasibility of obtaining cost data on a periodic basis from all ambulance providers of services and suppliers for potential use in examining the appropriateness of the Medicare add-on payments for ground ambulance services furnished under the fee schedule under section 1834(1) of

the Act and in preparing for future reform of such payment system. We therefore invited public comment on these issues as part of the study we are conducting under section 604(d)(1)(B) of the ATRA.

Several organizations provided detailed comments on the issues described above. We appreciate the commenters' insights and suggestions. We will consider those comments as we perform the study required by section 604(d)(1)(B) of the ATRA and prepare the Report to Congress.

E. Policies Regarding the Clinical Laboratory Fee Schedule

1. Background on the Clinical Laboratory Fee Schedule

Under Medicare Part B, clinical diagnostic laboratory tests furnished on or after July 1, 1984, in a physician's office, by an independent laboratory, or by a hospital laboratory for its outpatients and nonpatients are paid on the basis of the Clinical Laboratory Fee Schedule (CLFS), with certain exceptions. For each Healthcare Common Procedure Coding System (HCPCS) code, payment is the lesser of:

- The amount of charges billed for the test;
- The fee schedule amount for the state or a local geographic area; or
- A national limitation amount (NLA)

(see section 1833(a)(1)(D)(i), (a)(2)(D)(i), (h)(1), and (h)(4)(B) of the Act). The NLA for a clinical diagnostic laboratory test performed after December 31, 1997 is equal to 74 percent of the median of all fee schedules established for that test for that laboratory setting or 100 percent of such median in the case of a clinical diagnostic laboratory test performed on or after January 1, 2001 that the Secretary determines is a new test for which no limitation amount has previously been established (see section 1833(h)(4)(B)(viii) of the Act).

Currently, we update the CLFS amounts annually to reflect changes in the Consumer Price Index for all Urban Consumers (CPI-U) and apply a multi-factor productivity adjustment (see section 1833(h)(2)(A) of the Act). In the past, we also implemented other adjustments or did not apply the change in the CPI-U to the CLFS for certain years in accordance with statutory mandates. We do not otherwise update or change the payment amounts for tests on the CLFS.

For any clinical diagnostic laboratory tests where a new or substantially revised HCPCS code is assigned on or after January 1, 2005, we determine the basis for, and amount of, payment for these clinical diagnostic laboratory tests (see section 1833(h)(8) of the Act and §414.500 through §414.509). Once established, however, in most cases, we only have the opportunity to reconsider the basis and/or amount of payment for new tests for one additional year after the basis or payment is initially set. Once the reconsideration process is complete, payment is not further adjusted (except by a change in the CPI-U, the productivity adjustment, and any other adjustments required by statute), regardless of any shift in the actual costs incurred to perform the test.

This lack of an established mechanism to adjust payment amounts is unique among the Medicare payment schedules and systems. Generally, other fee schedules and prospective payment systems are evaluated each year to reflect the changing mix of services provided under that system or schedule and then the system or schedule is adjusted to maintain budget neutrality. Since there is currently no process to make such adjustments for the CLFS, payment amounts are not changed despite changes in technology, which affect the cost of performing the tests. This potentially results in CMS not paying as accurately for these tests. As discussed in the CY 2014 PFS proposed rule (78 FR 43350 through 43352), we proposed to implement a process to adjust payment amounts based on changes in technology. Below, we discuss our proposals regarding this process and, at the end of section III.E.2. of this final rule with comment period, respond to comments about our proposals and finalize our policies.

- 2. Policies Regarding Technological Changes Under Section 1833(h)(2)(A)(i) of the Act
- a. Background on Technological Changes

As discussed in the CY 2014 PFS proposed rule (78 FR 43350 through 43351), there has been a significant amount of technological change in the clinical laboratory area since the implementation of the CLFS. This technological change has led to the increased use of point-of-care testing, brand new tests being developed, and the proliferation of laboratory-developed tests. The Institute of Medicine (IOM) dedicated a chapter of its 2000 report "Medicare Laboratory Payment Policy: Now and in the Future" to discussing trends in laboratory technology. The report noted rapid and dramatic innovation in the

laboratory sector since the 1980s and remarkable growth in the range and complexity of available tests.

The IOM concluded that the introduction of new tests, advances in equipment and testing techniques, and the proliferation of advanced information technology have all made testing more efficient and automated.

Technology has enabled a significant site-of-service shift for many laboratory tests from the laboratory environment to the point of health care delivery. This point-of-care testing has increased since the 1980s, when this type of testing first became available, mainly due to changes in technology which resulted in smaller, cheaper, and more portable test kits that are simple to use. For example, drug abuse testing has become readily available at the point-of-care. Point-of-care testing can be performed in various institutional and community settings but the main objective of such testing is to produce a result quickly, at the place where the patient is receiving care, such as at a physician's office or at a hospital bedside, in order to facilitate decisions about appropriate treatment.

There also are brand new technologies that did not exist when the CLFS was established, most notably the methods that are the basis for many genetic and genomic tests. Many of these methods evolved from the work of the Human Genome Project and subsequent research and development by both the federal government and private firms. The cost of sequencing a genome has dropped dramatically since the early inception of this technology in 2001 from more than \$95 million per genome to approximately \$5,700 in early 2013 (http://www.genome.gov/pages/der/sequencing_cost.xlsx). Early tests in this area were less likely to be covered by Medicare because they were either screening tests or tests for conditions found largely in a pediatric population. As this area has expanded over the past several decades, Medicare has taken on a more prominent role in payment for these services. We expect the number of codes and tests in this area to continue to grow as the technology evolves and more tests become available in the areas of pharmacogenomics, personalized and predictive medicine, and companion diagnostics. Moreover, we expect the costs of these tests to change over time, and we believe that the CLFS ought to be able to better reflect these changes.

We also note the growth in laboratory-developed tests (LDTs) over the years. These proprietary tests are developed by laboratories, which then offer the service of providing the test. Some of the most

advanced laboratory tests currently being performed are LDTs which use sophisticated proprietary technology. Many LDTs do not have their own HCPCS codes; instead, they are billed using unlisted codes for which Medicare Administrative Contractors (MACs) establish a payment amount for their local jurisdictions. Prior to 2012, other LDTs were billed to Medicare using "stacking codes," where a laboratory submits a code for each step of the testing process. These "stacking codes" were eliminated at the end of 2012 and replaced with new test-specific codes.

The use of unlisted CPT and "stacking" codes provided us with limited information about the technology used to perform these tests. However, we know that the number of LDTs has been growing over the years. We also know that multiple laboratories have developed different ways to perform the same test. Further, our recent experience with using a gapfilling methodology to price molecular pathology tests, which can be LDTs, has shown that the costs of performing these tests have decreased since contractors initially established payment amounts for the tests, or compared to the code stack previously billed. Our experience with gapfilling molecular pathology tests also has shown that there is wide variation in the cost of performing the same test by different laboratories.

We believe that, given the technological changes that have occurred in the laboratory industry over the past several decades and the growth in the number of clinical laboratory tests (for example, we have added approximately 800 new test codes to the CLFS since its inception), it would be appropriate to establish a process to reexamine payment amounts on the CLFS to take into account increased efficiency, changes in laboratory personnel and supplies necessary to conduct a test, changes in sites of service, and other changes driven by technological advances.

Section 1833(h)(2)(A)(i) of the Act requires the Secretary to set the fee schedules for clinical laboratory tests "for the 12-month period beginning July 1, 1984, adjusted annually (to become effective on January 1 of each year) by, subject to [the multi-factor productivity adjustment], ... a percentage increase or decrease equal to the percentage increase or decrease in the [CPI-U], ... and subject to such other adjustments as the Secretary determines are justified by technological changes" (emphasis added). Under this authority, in the CY 2014 PFS proposed rule (78 FR 43350 through 43352), we proposed a

process under which we would systematically reexamine the payment amounts established under the CLFS to determine if changes in technology for the delivery of that service warrant an adjustment to the payment amount.

b. Definition of Technological Changes

In the CY 2014 PFS proposed rule (78 FR 43351), we proposed to define technological changes as changes to the tools, machines, supplies, labor, instruments, skills, techniques, and devices by which laboratory tests are produced and used. We stated that changes in technology could result in changes to, among other things, the resources required to perform the test (such as the type, volume, or number of supplies or reagents required), the laboratory personnel required to perform the test, and/or the frequency of testing, volume of testing, or site of service (for example, a shift in service site from a specialty laboratory to a physician's office). We believe this broad definition would capture all of the technological changes that could impact the resource inputs for various tests on the CLFS. As we explained in the CY 2014 PFS proposed rule (78 FR 43351 and 43352) and as discussed below, the technological changes for a specific test would be discussed in the proposed rule in which we are proposing to adjust the payment amount for that test, and we would seek public comment on our determination of the technological changes and the proposed payment adjustment. We respond to any comments on the proposed definition at the end of section III.E.2. of this final rule with comment period.

c. The Process

In the CY 2014 PFS proposed rule (78 FR 43351), we proposed that, each year, we would review certain codes on the CLFS, as described in the next section, to determine whether we believe that payment for these codes should be adjusted due to technological changes. For those codes where we determine that payment adjustments should be made, beginning with the CY 2015 PFS proposed rule (which will be promulgated during 2014 and any finalized payment adjustments would affect payments beginning in CY 2015), we would identify the test code, discuss how it has been impacted by technological changes, and propose an associated adjustment to the payment amount for the test code as appropriate to reflect the impact of such technological changes.

We believe such adjustments could be made both to increase fee schedule amounts (for example, in situations where new high cost technologies are employed), and to provide for reductions in existing amounts (for example in situations where technology reduces costs through increased efficiencies). We stated that we expect that most payment amounts would decrease due to the changes in technology that have occurred over the years since the payment amounts were established and the general downward trend of costs once a new technology has had an opportunity to diffuse. A key goal in establishing this review process is to ensure payment accuracy after technological changes; thus, payment amounts could increase or decrease as a result of these reviews.

Under our proposed process, we would list codes that we reviewed for which there was insufficient information to support or establish an adjustment to the payment amount due to technological changes. We also would solicit comment on the technology used to perform any tests we reviewed for possible payment changes, and any relevant cost information. We stated that we expect that we would finalize any payment adjustments in the PFS final rule during 2014, which would affect payments beginning in CY 2015. We proposed that the CPI-U and multi-factor productivity adjustments would be applied after we established the new payment amount through our usual instruction process.

We believe that this proposed process would best allow for the greatest amount of transparency in review and the most structured and consistent opportunity for the public to provide input into the process. We solicited comment on these proposals. We respond to comments on this proposed process at the end of section III.E.2. of this final rule with comment period.

d. Identification and Prioritization of Codes to be Reviewed

In the CY 2014 PFS proposed rule (78 FR 43351 through 43352), we proposed to review all codes currently on the CLFS. We proposed to start our review by examining the payment amounts for codes that have been on the CLFS the longest and then work our way forward, over multiple years, until we have reviewed all of the codes on the CLFS. We believe that the payment amounts for codes that have been on the CLFS the longest amount of time would be most affected by changes in technology because, in general, technology is most expensive earliest in its life cycle but decreases in cost as the

technology matures and diffuses. If during the course of reviewing these individual codes we find that there are additional, newer codes that are clinically and/or technologically similar, we proposed to consider them for review at the same time as we review the older codes because we expect that we would have the same or similar justifications for making payment adjustments to those codes. We stated that we intend to review these codes as quickly as possible but we believe there would be a significant administrative burden associated with such a comprehensive review of the approximately 1,250 codes on the CLFS. We estimated that it would take at least 5 years to review all of the existing codes on the CLFS.

Once we completed our review of the codes currently on the CLFS and made any adjustments necessary due to technological changes, we proposed to review codes added to the CLFS after 2015 that have been on the CLFS for at least 5 years. We also would review codes again that have not been reviewed in the previous 5 years, as time and resources allow. We believe that tests that are less than 5 years old are likely still in their technological infancy and enough time would not have passed to adequately assess any change in technology for those services. Similarly, for previously reviewed codes, we believe that technology likely would not have changed dramatically in less than 5 years. We solicited public comment on how to prioritize these codes, which we expect to address in future rulemaking on this issue.

After the initial review of the codes currently on the CLFS, we also proposed to allow the public to nominate additional codes for review, including those that had been previously reviewed for technological change. We proposed that the public may nominate only codes that have been on the CLFS for at least 5 years and that have not been reviewed in the previous 5 years. Further, we proposed that the nomination must include an explanation from the nominator of the technological change in the service and the way that change affects its delivery. We would then consider these nominations and, in the **Federal Register** the following year, either propose a payment change based on technological changes or explain why we think such a change is not warranted at that time.

We proposed to codify the proposed definition of technological changes and the process at §414.511.

We solicited public comment on these proposals. We also solicited comment on alternative approaches to achieving our goal of paying appropriately for laboratory tests by accounting for changes in technology. Finally, we solicited comment on general trends in technology change in the laboratory industry and the health care sector in general. The following is a summary of the comments we received regarding our proposals for the CLFS in the CY 2014 PFS proposed rule:

<u>Comment</u>: Several commenters recommended that CMS reconsider its proposal to review and adjust CLFS payment amounts.

Response: The existing payment amounts on the CLFS have not been changed since they were first implemented (excluding changes for inflation and other statutory adjustments). In some cases, payment amounts have not changed for over 30 years (excluding changes for inflation and other statutory adjustments). Therefore, we believe it is necessary and important to review and adjust payment amounts based on technological changes for tests on the CLFS.

<u>Comment</u>: Several commenters were concerned about CMS developing a transparent process where the public, specifically laboratories, could participate in determining which test codes on the CLFS to revisit for payment purposes and provide input on technological changes with respect to a code being reviewed for adjustment. These commenters suggested that one solution might be some type of advisory committee made up of representatives from the laboratory industry and organized by CMS.

Response: We appreciate the comment and agree that the process to adjust payment amounts for tests on the CLFS based on technological changes should be a transparent one. However, developing a formal advisory committee would be a time-consuming and resource intensive process. We believe that we can accomplish the same purpose by utilizing the annual rulemaking cycle, which includes a comment period where the public can provide information on how the technology for providing clinical diagnostic laboratory tests has changed over time and suggestions for data to support revised payment amounts on particular test codes.

We agree that the public also should participate in determining which test codes should be reviewed. We proposed that, after the initial review of all of the test codes currently on the CLFS concludes, the public could nominate codes for review that have been on the CLFS for at least 5 years and that have not been reviewed in the previous 5 years. We also proposed that the nomination must include an explanation from the nominator of the technological change in the service and the way that change affects its delivery. However, based on these comments and upon further reflection, we are changing our proposal so that nominations are not limited to the time period after the initial review period or to certain types of test codes. Under our process, the public may nominate test codes that are on the CLFS for review during the public comment period to the proposed rule.

As we proposed for situations where the public nominates test codes, the nominator must include an explanation of the technological change in the service and the way the change affects its delivery because this information will assist us in determining whether the test code should move forward through the payment adjustment process. In addition, we are changing our proposal to require the nominator to provide any relevant cost information, as well because this information will assist us in determining an appropriate payment should the test code move forward through the payment adjustment process. CMS will retain the final authority in determining which test codes move forward through the payment revision process because, for example, some test codes may be suggested which do not have enough supporting information to justify payment rate revisions based on changes in technology or more test codes may be suggested for payment rate revisions than can possibly be addressed within one rulemaking cycle.

For those codes identified by the public for review where we determine that payment adjustments based on technological changes should be made, in the following year's proposed rule, we will identify the test code, discuss how it has been impacted by technological changes, and propose an associated adjustment to the payment amount for the test code as appropriate to reflect the impact of such technological changes. We also will list any test codes that the public suggested for review but for which we are not proposing to move forward through the payment revision process and explain why we are not proposing any changes at that time. Finalized payment revisions would take effect the following January

1. For example, test codes suggested during the comment period to the CY 2015 PFS proposed rule and agreed to by CMS for the payment revision process will be addressed through the CY 2016 PFS rulemaking process with finalized payment adjustments being effective January 1, 2016.

<u>Comment</u>: Several commenters, along with MedPAC, stated that, if CMS does implement changes in payment amounts for test codes on the CLFS, CMS should consider data from private insurers, federal insurers, and CMS contractors; however, some commenters suggested that contractor data not be used.

Response: It is our intention to consider data from all available sources in order to evaluate the impact of technological changes on payment amounts. We believe that this will promote fair and equitable fee schedules that reflect current and reasonable payments for laboratory tests. Therefore, we plan to review all data that can be obtained from any source.

<u>Comment</u>: Some commenters, along with MedPAC, suggested that CMS focus on high dollar payments first, while other commenters recommended a focus on codes with rapid spending growth. Some commenters recommended that a different timeframe be implemented instead of the proposed one which limits the ability to review a test code until it has been on the CLFS for at least 5 years. These commenters also believe that it will take longer than 5 years to review all the test codes currently on the CLFS.

Response: In the CY 2014 PFS proposed rule (78 FR 43351 through 43352), we proposed to review all codes currently on the CLFS and we proposed to start our review by examining the payment amounts for codes that have been on the CLFS the longest and then work our way forward over multiple years until we reviewed all of the codes on the CLFS. We also proposed to review newer codes that were clinically and/or technologically similar to the codes being reviewed. Once we had completed this initial review, which we estimated would take at least 5 years, we proposed to review codes added to the CLFS after 2015 that had been on the CLFS for at least 5 years and would review codes again that had not been reviewed in the previous 5 years, as time and resources allowed. Further, as discussed above, we proposed that the public could nominate additional codes for review after this initial review period that

had been on the CLFS for at least 5 years and had not been reviewed in the previous 5 years. We sought comment on these proposals as well as alternative approaches to achieving our goal of paying appropriately for laboratory tests by accounting for changes in technology. Upon further reflection and based on these comments, we are modifying our approach to the identification and prioritization of codes for review.

We agree with the commenters who suggest that our proposal limits the ability to review a test code until it has been on the CLFS for at least 5 years. While we believe that addressing test codes that have been on the CLFS at least 5 years provides ample time for the technology to mature and diffuse, we recognize that there are circumstances that would warrant examining test codes for the payment revision process prior to this time. For example, new technologies could be developed that make it more or less costly to perform a test within a timeframe that is less than 5 years. Consistent with commenters' suggestions, we also believe that we should expand the criteria for identifying and prioritizing test codes for review to include criteria, such as rapid spending growth, high dollar payment, and high volume, as well as the oldest test codes on the CLFS, among other considerations, rather than focusing on the oldest codes currently on the CLFS and codes that have been on the CLFS for at least 5 years. We believe that test codes that are most ripe for review will be test codes where the current payment amounts do not account for changes in technology that have occurred since the test code was added to the CLFS and where the adjustments to the payment amounts will have a significant impact on payments made under the CLFS. We believe that expanding and maintaining flexibility with respect to the criteria will assist us in identifying and prioritizing test codes which are most ripe for revision. We will determine which test codes are most ripe for review based on an analysis of the data for test codes on the CLFS.

Therefore, upon further reflection and based on these comments, we are finalizing a modified approach to identify and prioritize codes that will be reviewed every year. Each year, we will conduct a data analysis of codes on the CLFS to determine which codes should be proposed during the rulemaking cycle for a payment adjustment due to technological changes. This review will involve examining test codes in several different ways, such as examining those that have been on the CLFS the longest, those

that are high volume test codes, those that have a high dollar payment, or those that have experienced rapid spending growth, among other considerations. As proposed, if we identify codes that are clinically and/or technologically similar to the ones identified through our data analysis process, we will consider them for review at the same time as we review the related codes. As discussed previously, we also will allow the public to nominate codes for review.

<u>Comment</u>: Some commenters, along with MedPAC, asked that CMS not lower all payments and suggested that CMS must take into consideration the technological changes that may have added costs over the years.

Response: We will not be automatically lowering all payment amounts on the CLFS. Rather, test codes and corresponding payment amounts will be reviewed on a case-by-case basis to determine how changes in technology have affected the cost of the test. As we stated in the CY 2014 PFS proposed rule (78 FR 43351) and above in this final rule with comment period, we believe adjustments could be made to increase fee schedule amounts for certain tests (for example, in situations where new high cost technologies are employed), and to provide for reductions in existing amounts for other tests (for example in situations where technology reduces costs through increased efficiencies). A key goal in establishing this review process is to increase payment accuracy after technological changes; thus, payment amounts could increase or decrease as a result of these reviews.

<u>Comment</u>: Some commenters recommended that CMS proceed through negotiated rulemaking, so that interested stakeholders will have a say in the process.

Response: Similar to what we stated above regarding a formal advisory committee, we believe that using a negotiated rulemaking vehicle would be a time-consuming and resource intensive process. We believe that we can accomplish the same purpose by utilizing the rulemaking process, under which we would propose payment revisions for identified test codes and provide a comment period during which the public could comment prior to the publication of the final rule (which would finalize any payment changes). During the comment period, the public can nominate codes for review, provide information on how the technology for providing clinical diagnostic laboratory tests has changed over

time and suggest data to support revised payment amounts for particular test codes. Therefore, our annual rulemaking process will provide the public with ample opportunity to comment and interact with us as the process proceeds. CMS will retain the final authority in determining which test codes move forward through the payment revision process.

<u>Comment</u>: Several commenters suggested that the amount of a payment adjustment should be capped during the first year, and any remaining payment adjustment should be phased in over a number of years so that smaller laboratories or laboratories that offer only a small menu of tests would be minimally disrupted.

Response: While we recognize that laboratories of different sizes or specialties may respond differently to market forces, our goal is to adjust payment amounts for test codes up for consideration in a given year as soon as possible to more accurately reflect the costs of these tests based on changes in technology. Laboratories that may be affected by the examination of a payment amount for any specific test code will have the opportunity to comment through the rulemaking process.

<u>Comment</u>: Many commenters suggested that CMS recognize the difference between large and small laboratories so that small laboratories will not be phased out or forced out of business.

Response: It is not our intention to eliminate or phase out any organization or business. Our goal is to adjust the payment amounts for tests on the CLFS to more accurately reflect the costs of tests based on technological changes, which should result in payment amounts under the CLFS being more commensurate with the current costs of providing these tests.

<u>Comment</u>: Several commenters recommended that CMS send proposed adjustments out to interested parties prior to any final decisions for feedback.

Response: We agree that we need to provide notice and an opportunity to comment on proposed adjustments to the fee schedules due to technological changes to interested parties prior to finalizing these adjustments and we believe that our proposed process, which we are finalizing, does this. Specifically, the rulemaking process would propose payment revisions for the identified test codes and provide a comment period during which the public could comment prior to the publication of the final rule (which

would finalize any payment adjustments). Therefore, as proposed, we will utilize the rulemaking process with a comment period so that the public can provide information on how the technology of providing clinical diagnostic laboratory tests has changed over time and suggestions for data to support revised payment amounts on particular test codes.

<u>Comment</u>: Some commenters suggested creating a pilot program, a demonstration project, or competitive bidding for changing the payment amounts for codes on the CLFS.

Response: We believe, similar to our response above concerning either a negotiated rulemaking process or an advisory board, that developing anything formal such as a pilot program, a demonstration project, or competitive bidding would be a time-consuming and resource intensive process. We believe that we can accomplish the same purpose by utilizing the rulemaking process with a comment period where the public can nominate test codes for review, provide information on how the technology for delivering clinical diagnostic laboratory services has changed over time and suggest data to support revised payment amounts on particular test codes.

After considering all of the comments received, we are finalizing our proposal without modification to define technological changes as changes to the tools, machines, supplies, labor, instruments, skills, techniques, and devices by which laboratory tests are produced and used. We are finalizing our proposed process, including the prioritization of codes for review, with modification as discussed above and noted below.

Each year, we will conduct a data analysis of codes on the CLFS to determine which codes should be proposed during the rulemaking cycle for a payment adjustment due to technological changes. This review will involve examining test codes in several different ways, such as examining those that have been on the CLFS the longest, those that are high volume test codes, those that have a high dollar payment, or those that have experienced rapid spending growth, among other considerations. If we identify codes that are clinically and/or technologically similar to the ones identified through our data analysis process, we will consider them for review at the same time as we review the related codes.

For those codes where we determine that payment adjustments should be made, beginning with the CY 2015 PFS proposed rule (which will be promulgated during 2014 and any finalized payment adjustments would affect payments beginning CY 2015), we will identify the test code, discuss how the test has been impacted by technological changes, and propose an associated adjustment to the payment amount for the test code as appropriate to reflect the impact of such technological changes. We will solicit comment on the technology used to perform any tests we reviewed for possible payment changes, and any relevant cost information.

Under our process, the public may nominate test codes that are on the CLFS for review during the public comment period to the proposed rule. Test codes nominated for review by the public must include an explanation from the nominator of the technological change in the service and the way that change affects its delivery as well as any relevant cost information. CMS will retain the final authority in determining which test codes move forward through the payment revision process. For those codes identified by the public for review where we determine that payment adjustments based on technological changes should be made, in the following year's proposed rule, we will identify the test code, discuss how it has been impacted by technological changes, and propose an associated adjustment to the payment amount for the test code as appropriate to reflect the impact of such technological changes. We also will list any test codes that the public suggested for review but for which we are not proposing to move forward through the payment revision process and explain why we are not proposing any changes at that time. Finalized payment revisions would take effect the following January 1. For example, test codes suggested during the comment period to the CY 2015 PFS proposed rule and agreed to by CMS for the payment revision process will be addressed through the CY 2016 PFS rulemaking process with finalized payment adjustments being effective January 1, 2016. The CPI-U and multi-factor productivity adjustments will be applied after we establish the new payment amount through our

usual instruction process.

Finally, we are codifying our proposed definition of technological changes and the process at §414.511 with one technical correction. In §414.511(a), we are adding the words "fee schedules," which we inadvertently omitted in the proposed rule.

3. Changes in the CY 2014 OPPS/ASC Final Rule with Comment Period

In the CY 2014 PFS proposed rule (78 FR 43352), we notified readers that we were proposing to package payment for certain clinical diagnostic laboratory tests into the Ambulatory Payment Classification (APC) group payment for the significant procedures and services with which those laboratory tests are billed in the CY 2014 OPPS/ASC proposed rule. We discussed this proposal in the section on "Proposed Changes to Packaged Items and Services" in the CY 2014 OPPS/ASC proposed rule. For details on the final policy, please see the "Changes to Packaged Items and Services" section of the CY 2014 OPPS/ASC final rule with comment period.

F. <u>Liability for Overpayments to or on Behalf of Individuals including Payments to Providers or Other</u>

Persons

1. Background and Statutory Authority

CMS waives recovery of overpayments in certain situations for claims based fee-for-service provider, supplier or beneficiary overpayments in accordance with section 1870 of the Act. Section 1870(b) and (c) of the Act provide a waiver of recovery of provider, supplier or beneficiary overpayments under certain presumptions within a specified timeframe. Section 1870(b) and (c) of the Act allow the Secretary to reduce the specified time period to not less than 1 year if the Secretary finds that such a reduction is consistent with the objectives of the Medicare program. Section 638 of the American Taxpayer Relief Act of 2012 (ATRA) (Pub. L. 112–240, enacted January 2, 2013) changed the timeframes associated with section 1870(b) and (c) of the Act.

Section 1870(b) of the Act provides for the waiver of recovery of an overpayment to a provider of services (hereinafter, "provider") or other person whenever that provider or other person is "without fault" in incurring the overpayment. For purposes of section 1870 of the Act and this final rule with comment period, the term "other person" includes practitioners, physicians, and other suppliers.

Section 1870(b) of the Act also establishes circumstances under which a provider or other person is presumed for administrative purposes to be "without fault" for an overpayment. If an overpayment is determined after a specified period of time, a provider or other person is presumed to be "without fault." This presumption is negated, however, if there is evidence to show that the provider or other person was responsible for causing the overpayment.

Section 1870(c) of the Act provides for the waiver of recovery of an overpayment to an individual whenever the individual is "without fault" in incurring the overpayment, and recovery would either defeat the purpose of the Social Security or Medicare programs or would be "against equity and good conscience."

Section 1870(c) of the Act also establishes circumstances under which recovery of an overpayment for an individual is presumed to be "against equity and good conscience." After a specified

period of time, recovery of certain overpayments from individuals who are "without fault" is presumed "against equity and good conscience." The overpayments addressed by this provision are payments for items or services for which payment may not be made because of the prohibitions found in section 1862(a)(1) or (a)(9) of the Act. Sections 1862(a)(1) and (a)(9) prohibit payment for, among other things, items and services that are not reasonable and necessary or that are for custodial care.

Section 638 of the ATRA amended the timeframe specified in section 1870(b) of the Act "without fault" presumption from 3 to 5 years so that the presumption of "without fault" only applies if the Medicare claims based fee-for-service overpayment determination for a provider or other person is made subsequent to the fifth year (instead of the third year) following the year in which the notice was sent to such individual that such amount had been paid. Likewise, section 638 of the ATRA amended the timeframe in section 1870(c) of the Act so that the presumption for "against equity and good conscience" for certain types of denials for an individual who is "without fault" only applies if the overpayment determination is made subsequent to the fifth year (instead of the third year) following the year in which notice of such payment was sent to such individual.

These ATRA changes do not affect or change CMS' claims reopening regulation at §405.980. Specifically, we retain our authority to reopen claims for any reason within 1 year, for good cause within 4 years, and at any time for fraud or similar fault.

2. Provisions of the Proposed Regulations

We proposed to revise §405.350(c) and §405.355(b). These revisions would change the timing of the triggering event for the "without fault" and "against equity and good conscience" presumptions.

These revisions reflect the revisions to section 1870 of the Act as specified in section 638 of ATRA.

Specifically, we proposed to change the timeframe at §405.350(c) so that the rebuttable "without fault" presumption for the provider or other person would apply if the Medicare claims based fee-for-service overpayment determination is made subsequent to the fifth year (instead of the third year) following the year in which the notice was sent to such individual that such amount had been paid.

Likewise, we proposed to amend the timeframe at §405.355(b) for the presumption "against equity and good conscience" for certain types of denials for an individual who is "without fault" so that the presumption would apply if the overpayment determination is made subsequent to the fifth year (instead of the third year) following the year in which the notice of payment was sent to the individual.

Additionally, in our review of the current regulation implementing section 1870(c) of the Act, we noted that §405.355(b) does not clearly reflect the statutory language, which limits the "against equity and good conscience" presumption to overpayments associated with denials under section 1862(a)(1) or (a)(9) of the Act. Accordingly, we proposed to update and clarify §405.355(b) so that it clearly reflects the statutory language by adding that the "against equity and good conscience" presumption would be applicable for an individual who is "without fault" only if the overpayment is related to items and services that are not payable under section 1862(a)(1) or (a)(9) of the Act. In addition, we proposed to delete the parenthetical at the end of §405.355(b) because the regulations referenced no longer exist; those sections of the regulations were reassigned. (See the October 11, 1989 **Federal Register** (54 FR 41733).) The modifications we proposed to §405.355(b) make the references in the parenthetical no longer necessary.

The following is a summary of the comments we received regarding our proposals.

Comment: Commenters were opposed to CMS changing the timeframe for the "without fault" presumptions in §405.350(c) and §405.355(b) from 3 years to 5 years. These commenters expressed concern that changing the timeframe would require physicians to be subject to audits, recovery initiatives, and other undue burdens, including onerous record-keeping requirements, for an additional 2 years despite inadvertently or unknowingly receiving the overpayments.

Response: We are finalizing the revisions to the regulations as proposed and changing the timeframe for the "without fault" presumptions from 3 years to 5 years as specified in section 638 of ATRA. Although the Secretary has the <u>authority</u> to reduce the 5-year timeframe to not less than 1 year consistent with the objectives of the program, we do not believe that the Secretary has any basis for such reduction at this time, particularly in light of the Congressional intent expressed by the ATRA provisions.

In addition, although section 638 of ATRA changed the timeframe for the "without fault" presumptions, ATRA did not change CMS' claims reopening timeframes. (In accordance with §405.980, claims may be reopened within 1 year for any reason, up to 4 years for good cause, and at any time for fraud or similar fault.) We believe maintaining the existing claim reopening timeframes will alleviate the commenters concerns about an increased burden.

We did not receive any comments on our proposals to edit §405.355(b). Specifically, we proposed to (1) update and clarify §405.355(b) so that it clearly reflects the statutory language and (2) delete the parenthetical at the end of §405.355(b) because the regulations referenced no longer exists. We are finalizing the updates to §405.355(b) as proposed.

G. Physician Compare Website

1. Background and Statutory Authority

Section 10331(a)(1) of the Affordable Care Act, requires that, by no later than January 1, 2011, we develop a Physician Compare Internet website with information on physicians enrolled in the Medicare program under section 1866(j) of the Act, as well as information on other eligible professionals who participate in the Physician Quality Reporting System (PQRS) under section 1848 of the Act.

CMS launched the first phase of Physician Compare on December 30, 2010 (www.medicare.gov/physiciancompare). In the initial phase, we posted the names of eligible professionals that satisfactorily submitted quality data for the 2009 PQRS, as required by section 1848(m)(5)(G) of the Act.

Section 10331(a)(2) of the Affordable Care Act also requires that, no later than January 1, 2013, and for reporting periods that begin no earlier than January 1, 2012, we implement a plan for making publicly available through Physician Compare information on physician performance that provides comparable information on quality and patient experience measures. We met this requirement in advance of January 1, 2013, as outlined below, and intend to continue to address elements of the plan through rulemaking.

To the extent that scientifically sound measures are developed and are available, we are required to include, to the extent practicable, the following types of measures for public reporting:

- Measures collected under the PQRS.
- An assessment of patient health outcomes and functional status of patients.
- An assessment of the continuity and coordination of care and care transitions, including episodes of care and risk-adjusted resource use.
 - An assessment of efficiency.
 - An assessment of patient experience and patient, caregiver, and family engagement.
 - An assessment of the safety, effectiveness, and timeliness of care.
 - Other information as determined appropriate by the Secretary.

As required under section 10331(b) of the Affordable Care Act, in developing and implementing the plan, we must include, to the extent practicable, the following:

- Processes to ensure that data made public are statistically valid, reliable, and accurate, including risk adjustment mechanisms used by the Secretary.
- Processes for physicians and eligible professionals whose information is being publicly reported to have a reasonable opportunity, as determined by the Secretary, to review their results before posting to Physician Compare. This would consist of a 30-day preview period for all measurement performance data that will allow physicians and other eligible professionals to view their data as it will appear on the website in advance of publication. Details of the preview process will be communicated on the Physician Compare Initiative page on CMS.gov in advance of the preview period.
- Processes to ensure the data published on Physician Compare provides a robust and accurate portrayal of a physician's performance.
- Data that reflects the care provided to all patients seen by physicians, under both the Medicare program and, to the extent applicable, other payers, to the extent such information would provide a more accurate portrayal of physician performance.
- Processes to ensure appropriate attribution of care when multiple physicians and other providers are involved in the care of the patient.
- Processes to ensure timely statistical performance feedback is provided to physicians concerning the data published on Physician Compare.
- Implementation of computer and data infrastructure and systems used to support valid, reliable and accurate reporting activities.

Section 10331(d) of the Affordable Care Act requires us to consider input from multi-stakeholder groups in selecting quality measures for Physician Compare, which we are working to accomplish through a variety of means including rulemaking and various forms of stakeholder outreach. In developing the plan for making information on physician performance publicly available through Physician Compare, section 10331(e) of the Affordable Care Act requires the Secretary, as the Secretary

deems appropriate, to consider the plan to transition to value-based purchasing for physicians and other practitioners that was developed under section 131(d) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110-275, enacted on July 15, 2008).

Under section 10331(f) of the Affordable Care Act, we are required to submit a report to the Congress, by January 1, 2015, on Physician Compare development, and include information on the efforts and plans to collect and publish data on physician quality and efficiency and on patient experience of care in support of value-based purchasing and consumer choice. Initial work on this report is currently underway. Section 10331(g) of the Affordable Care Act provides that any time before that date, we may continue to expand the information made available on Physician Compare.

We believe section 10331 of the Affordable Care Act supports our overarching goals of providing consumers with quality of care information to make informed decisions about their healthcare, while encouraging clinicians to improve on the quality of care they provide to their patients. In accordance with section 10331 of the Affordable Care Act, we intend to utilize Physician Compare to publicly report physician performance results.

2. Public Reporting of Physician Performance Data

Since the initial launch of the website, we have continued to build on and improve Physician Compare. In 2013, we launched a full redesign of Physician Compare offering significant improvements including a complete overhaul of the underlying database and a new Intelligent Search feature, addressing two of our stakeholders' primary critiques of the site and considerably improving functionality and usability. The primary source of administrative information on Physician Compare is the Provider Enrollment, Chain, and Ownership System (PECOS); as the sole source of verified Medicare professional information, PECOS remains the primary information source. However, with the redesign, we incorporated the use of Medicare claims information to verify the information in PECOS to ensure only the most current and accurate information is included on the site. The following is a summary of general comments we received about the website and its redesign.

<u>Comment</u>: We received positive comments regarding our use of Medicare claims to verify information in PECOS; however, some commenters did express concerns with lingering data issues regarding basic demographic information, specialty classification, and hospital affiliation. Some commenters urged CMS to address these concerns prior to posting quality measure performance information on the site. Other commenters requested we implement a streamlined process by which professionals can correct their information in a timely manner.

Response: We appreciate the commenters' feedback regarding concerns over the accuracy of the information currently available on Physician Compare. CMS is committed to including accurate and upto-date information on Physician Compare and continues to work to make improvements to the information presented.

The underlying database on Physician Compare is generated from the PECOS as well as Fee-For-Service (FFS) claims and it is therefore critical that physicians, other healthcare professionals, and group practices ensure that their information is up-to-date and as complete as possible in the national PECOS database. Currently, the most immediate way to address inaccurate PECOS data on Physician Compare is by updating information via Internet-based PECOS at https://pecos.cms.hhs.gov/pecos/login.do. Please note that the specialties as reported on Physician Compare are those specialties reported to Medicare when a physician or other healthcare professional enrolls in Medicare and are limited to the specialties noted on the 855i Enrollment Form. And, all addresses listed on Physician Compare must be entered in and verified in PECOS. To update information not found in PECOS, such as hospital affiliation and foreign language, professionals and group practices should contact the Physician Compare team directly at physiciancompare@westat.com. Understanding the value of a more real-time option for updating information on Physician Compare and the ability to update all information in one place, we are evaluating the feasibility of such a mechanism for potential future development.

The following is a summary of the comments we received regarding the new Intelligent Search functionality:

Comment: We received comments concerning primary care specialties being listed with other specialties in the search results. One commenter noted that when they conducted a search for "neurosurgery" they were directed to select names of physicians from family practice, neurology and then neurosurgery - in that order. One commenter who searched for "general surgeons" was surprised that thirteen primary care physicians were listed as related to general surgery. Another commenter requested that CMS remove the "Search all Family Practice, General Practice, Geriatric Medicine, Internal Medicine, and Primary Healthcare Professionals" option as a result from searches for a specific type of specialist. They also requested that for searches where primary care may be applicable but not most appropriate, the all primary care option should be listed last.

Response: The purpose of Physician Compare is to connect users with a comprehensive list of physicians and other healthcare professionals that are capable of assisting them with their health-related concerns. Since primary care is generally the principal point of consultation for patients within the Medicare system, a link to search for all primary care specialties is always offered to patients as an option in the drop down list and/or results list. Based on feedback from both stakeholders and consumers received since the functionality went live, we are reevaluating how this information is presented on the site so it does not appear, for instance, that when you search for "neurosurgery" you are seeing primary care physicians because they are related to neurosurgery.

<u>Comment</u>: Some commenters felt that the search results were too broad and not actionable for patients. Commenters requested that CMS work with stakeholders such as state and national specialty societies to improve the accuracy of Physician Compare in associating specialists with different body parts and diseases.

Response: We appreciate the commenters' feedback on the Intelligent Search functionality. The development of this search function is an ongoing process and it will continue to evolve through quarterly updates. CMS values the input of stakeholders concerning the Intelligent Search. The Physician Compare team worked closely with specialty societies in the development of the initial Intelligent Search

function and continues to seek input and conduct outreach to ensure that the terms and phrases powering the search function are as comprehensive and accurate as possible.

<u>Comment</u>: One commenter noted that the search function for group practices does not work, citing that if one enters a zip code that is close to the group practice's primary address, the group practice does not appear.

Response: Search results are displayed on the website based on proximity to the center of the location searched, therefore search results may vary depending on if a zip code or a city/state search is conducted. In addition, the search results are generated using an auto-expand feature. The distance will vary depending on the location and type of search. All searches start at one mile and if less than 10 individuals or groups are found within that distance, the search radius will automatically expand incrementally until it reaches a sufficient amount of results. If sufficient results are returned, however, the search will not expand. This may lead to a group practice nearby not being displayed because there are a sufficient number of practices closer to the center of the search radius to satisfy the search.

Currently, users can view information about approved Medicare professionals such as name, primary and secondary specialties, practice locations, group affiliations, hospital affiliations that link to the hospital's profile on Hospital Compare as available, Medicare Assignment status, education, languages spoken, and American Board of Medical Specialties (ABMS) board certification information. In addition, for group practices, users can also view group practice names, specialties, practice locations, Medicare Assignment status, and affiliated professionals.

<u>Comment</u>: We received two comments regarding the publication of the ABMS board certification information. One commenter suggested that we add additional information on board certification such as contextual information regarding the certification process, as well as identifying the certifying Board and not just the specialty. Another commenter urged CMS to include other board's certifications, in addition to ABMS.

Response: We appreciate the commenters' feedback. We will evaluate the feasibility of including a link to the ABMS website so that users can get additional information about certification, as

well as certifying board information. And, we will evaluate the feasibility of potentially including data on Physician Compare from other board certification sources in a future website release, if the information is available and it is technically feasible.

As required by 1848(m)(5)(G) of the Act, we are required to post on a CMS website the names of eligible professionals who satisfactorily report under the PQRS, as well as those eligible professionals who are successful electronic prescribers under the Medicare Electronic Prescribing (eRx) Incentive Program. Physician Compare contains a link to the list of those names. In addition to the list of names, there is a section on each individual's profile page listing the quality programs under which the specific individual satisfactorily reported or if the individual was a successful electronic prescriber. The program name is listed and a green check mark clearly indicates which programs the individual satisfactorily or successfully participated in. These data will be updated annually with the most recent data available.

With the Physician Compare redesign, we have also added a quality programs section to each group practice profile page in order to indicate which group practices are satisfactorily reporting in Group Practice Reporting Option (GPRO) under the PQRS or are successful electronic prescribers under the eRx Incentive program. We have also included a notation and check mark for individuals that successfully participate in the Medicare EHR Incentive Program, as authorized by section 1848(o)(3)(D) of the Act. These data will be updated with the most recent data available.

<u>Comment</u>: One commenter urged CMS to reconsider its decision to publicly report on meaningful use data due to the ongoing issues related to the EHR program--including unresolved challenges related to interoperability of certified systems, concerns about the relevancy of meaningful use objectives to certain providers, and the large investment associated with EHR adoption that continues to make it cost prohibitive for small practices despite incentives.

Response: We appreciate the commenter's feedback on including EHR participation information. However, as this proposal was previously finalized, these data are currently available on Physician Compare. We believe the benefits of including these data, the growth of the program, and consumer interest in EHR adoption warrant the inclusion of these data on Physician Compare.

As we finalized in the 2013 PFS final rule with comment period (77 FR 69166), we will include the names of those eligible professionals who report the PQRS Cardiovascular Prevention measures group in support of the Million Hearts Initiative by including a check mark in the quality programs section of the profile page. Finally, we will also indicate in this manner those individuals who have earned the PQRS Maintenance of Certification Incentive starting with data reported for CY 2013. We will update this information annually moving forward.

<u>Comment</u>: One commenter requested that American Board of Optometry (ABO) certified optometrists who earn the PQRS MOC bonus be recognized on the Physician Compare website.

Response: We appreciate the commenter's feedback on including an indication on Physician Compare for participation in the additional PQRS Maintenance of Certification incentive for Optometrists. As all successful participants in the additional PQRS Maintenance of Certification incentive will have an indication of their participation on Physician Compare, this information will be included on the site when the information is published.

We are now instituting our plan for a phased approach to public reporting of performance information on Physician Compare. The first phase of our plan was finalized with the 2012 PFS final rule with comment period (77 FR 69166), where we established that PQRS GPRO measures collected through the GPRO web interface during 2012 would be publicly reported on Physician Compare. These measures will be publicly reported on Physician Compare in early CY 2014. We expanded our plan with the 2013 PFS final rule with comment period (77 FR 69166) where we established that the specific GPRO web interface measures that would be posted on Physician Compare include the Diabetes Mellitus (DM) and Coronary Artery Disease (CAD) PQRS GPRO measures, and that we would develop and report composite measures for these measure groups in future years, if technically feasible. Data reported in 2013 under the GPRO DM and GPRO CAD measures and composites collected via the GPRO web interface that meet the minimum sample size of 20 patients, and that prove to be statistically valid and reliable, will be publicly reported on Physician Compare in late CY 2014, if technically feasible. As we previously established, if the minimum threshold is not met for a particular measure, or the measure is

otherwise deemed not to be suitable for public reporting, the group's performance rate on that measure will not be publicly reported.

<u>Comment</u>: Several commenters requested CMS ensure the data reported on Physician Compare be accurate and reliable, citing that inaccurate data can damage physicians' reputations, result in false assumptions about care, and potentially lead to harmful consequences for patients. Commenters also strongly urged CMS to risk adjust the measures. Some commenters noted that there is an overreliance on process measures that are not linked to outcomes and that provide minimal value to consumers in comparing providers, or for assuring that physicians are providing high quality care.

Response: We appreciate the commenters' feedback, and understand their concerns. As required under section 10331(b) of the Affordable Care Act, in developing and implementing the plan to include performance data on Physician Compare, we must include, to the extent practicable, processes to ensure that the posted data are statistically valid, reliable, and accurate, including risk adjustment mechanisms used by the Secretary, as well as processes to ensure appropriate attribution of care when multiple providers are involved in the care of the patient. We understand that this information is complex, and are committed to providing data on Physician Compare that are useful to beneficiaries in assisting them in making informed healthcare decisions, while being accurate, valid, reliable, and complete. We will closely evaluate all quality measures under consideration for public reporting on the website to ensure they are presented in a way that is helpful to beneficiaries and, through consumer testing and stakeholder outreach, work to present this information in an accurate and user-friendly way. We also appreciate the commenters' feedback and understand the interest in focusing more on patient-centered outcome measures versus process measures. CMS will take this feedback into consideration for future rulemaking.

In the Medicare Shared Savings Program final rule (76 FR 67948), we noted that because Accountable Care Organization (ACO) providers/suppliers that are eligible professionals are considered to be a group practice for purposes of qualifying for a PQRS incentive under the Shared Savings Program, we would publicly report ACO performance on quality measures on Physician Compare in the same way

as we report performance on quality measures for PQRS GPRO group practices. Public reporting of performance on these measures will be presented at the ACO level only.

As part of our public reporting plan, in the CY 2013 PFS final rule with comment period (77 FR 69167), we also finalized our decision to publicly report Clinician and Group Consumer Assessment of Healthcare Providers and Systems (CG-CAHPS) data for group practices of 100 or more eligible professionals reporting data in 2013 under the GPRO, and for ACOs participating in the Shared Savings Program. We anticipate posting these data on Physician Compare as early as 2014.

3. Future Development of Physician Compare

We will continue to phase in an expansion of Physician Compare over the next several years by incorporating quality measures from a variety of sources, as technically feasible. We previously finalized a decision to publicly report on Physician Compare the performance rates on a limited set of web interface quality measures that group practices submit under the 2012 and 2013 PQRS GPRO web interface (76 FR 73417 and 77 FR 69166).

For 2014, we proposed to expand the quality measures posted on Physician Compare by publicly reporting in CY 2015 performance on all measures collected through the GPRO web interface for groups of all sizes participating in 2014 under the PQRS GPRO and for ACOs participating in the Medicare Shared Savings Program (78 FR 43354). These data would include measure performance rates for measures reported that met the minimum sample size of 20 patients, and that prove to be statistically valid and reliable. We noted we will provide a 30-day preview period prior to publication of quality data on Physician Compare so that group practices and ACOs can view their data as it will appear on Physician Compare before it is publicly reported, and that we will detail the process for the 30-day preview and provide a detailed timeline and instructions for preview in advance of the start of the preview period.

<u>Comment</u>: We received both positive and negative comments regarding our proposal to expand public reporting to all performance measures collected through the GPRO web interface. Commenters in support of the expansion highlight that it will be easier to identify a core set of measures on which to gauge a group practice's overall rate of performance. Another commenter noted that the expansion will

allow Physician Compare to report a wider selection of useful, actionable information to assist consumers in making informed choices about where they receive their care. Commenters opposed to the expansion felt that Physician Compare should revert to its original proposal to initially only report on a limited set of web interface measures noting that the public reporting of performance data should occur gradually and carefully to ensure the data are accurate and presented in a format that is easy to understand, meaningful, and actionable for consumers. Another commenter noted that the public reporting of physician performance data is a new undertaking for both CMS and the public and could have serious implications if it is not executed appropriately.

Response: We appreciate the commenters' feedback. We proposed an expanded set of web interface measures in 2014 as these measures provide an opportunity for more group practices to be able to have relevant data publically reported on Physician Compare and because this will provide consumers with more information to help them make informed healthcare decisions. Regarding concerns about gradually and carefully including additional quality of care information, 2014 will be the third year of data publicly reported on Physician Compare. The previous 2 years of public reporting will provide experience using a limited set of measures, allowing CMS to ensure an appropriate process and accurate data. Moving to a greater number of measures in 2014 is part of a gradual and phased approach. Also, CMS has been working to ensure the data are presented in a way that is both accurate and most useful to consumers through consumer testing and stakeholder outreach, starting with the 2012 data. Therefore, sufficient work in this area is being conducted to ensure the data are properly reported. We are thus finalizing this proposal to expand the quality measures posted on Physician Compare by publicly reporting in CY 2015 performance on all measures collected through the GPRO web interface for groups of all sizes participating in 2014 under the PORS GPRO. For ACOs participating in the Medicare Shared Savings Program, performance on the ACO GPRO measures will be reported publicly on Physician Compare in the same manner as group practices that report under the PQRS GPRO (76 FR 67948).

<u>Comment</u>: We received several comments in support of the 30-day preview period prior to publication of quality data. Many commenters urged CMS to allow physicians, group practices, and

ACOs the opportunity to correct and/or appeal any errors found in the performance information before it is posted on the site. Other commenters felt that a 30-day preview period was insufficient and requested that CMS extend the period up to 45, 60, or 90 days. One commenter recommends that CMS allow a preview period prior to any information being added to the website.

Response: We appreciate the commenters' feedback in support of the 30-day preview period for quality measures on Physician Compare. This 30-day period is in line with the preview period provided for other public reporting programs such as Hospital Compare. We will provide a 30-day preview period for confidential measure preview. If measure data have been collected and the measure has been deemed suitable for pubic reporting, the data will be published on Physician Compare. As such, there will not be a formal appeals process. However, if an error is found in the measure display during the preview period, there will be options to contact the Physician Compare team by both phone and e-mail. Errors will be corrected prior to publication.

We also appreciate the commenters' feedback regarding extending the 30-day preview period for quality measures on Physician Compare. However, due to our commitment to make this information available to the public in as timely a manner as possible and the website development timeline, a longer preview period is not possible at this time. Groups and individuals that will have measure data posted will be informed in advance of the preview period and the logistics necessary to access the confidential preview, review their data, and contact the Physician Compare team if needed. We believe this 30-day period provides ample time to accomplish these goals as evidenced by other programs, such as Hospital Compare.

At this time it is not feasible to incorporate a 30-day preview period for non-measure data, such as address, phone number, specialty, etc., included on the Physician Compare website as this would produce an unacceptable lag and limit our ability to provide up-to-date information to consumers that can assist them in making informed healthcare decisions.

We also received comments regarding the patient sample size of 20 patients. A patient sample size of 20 patients was previously finalized (77 FR 69166) for publication of the Diabetes and CAD

measures. As we are now expanding the PQRS GPRO measures available for public reporting on Physician Compare, this sample size would also apply to this expanded set of measures.

<u>Comment</u>: Two commenters expressed their concerns regarding the minimum patient sample size, citing that using such a small sample size will result in inaccurate and misleading information regarding the actual activities of the physician practice. One commenter recommended that we raise the sample size to 30. Another noted it was important to include sample size information on Physician Compare to help users better understand the measures being reported.

Response: We appreciate the commenters' feedback regarding the patient sample size and including this information on Physician Compare. We are committed to reporting quality of care data that is statistically valid, reliable, and accurate, and will only post data that meet this standard of reliability regardless of threshold, and regardless of measure type. Should we find a measure meeting the minimum threshold to be invalid or unreliable for any reason, the measure will not be reported.

We believe this threshold of 20 patients is sufficient. It is a large enough sample to protect patient privacy for reporting on the site, and it is the reliability threshold previously finalized for both the Value-Based Modifier (VBM) and the PQRS criteria for reporting measure groups (77 FR 69166). As we work to align quality initiatives and minimize reporting burden on physicians and other healthcare professionals, we are finalizing a patient sample size of 20 patients for the expanded set of PQRS GPRO measures available for public reporting on Physician Compare.

For 2013, we expanded PQRS GPRO to include a registry reporting option (77 FR 69166). For 2014, we are expanding the PQRS GPRO further to include an option to report data via EHR. Consistent with the requirement under section 10331(a)(2)(A) of the Affordable Care Act to make publicly available information on quality measures submitted by physicians and other eligible professionals under PQRS, we proposed to publicly report on Physician Compare performance on certain measures that groups report via registries and EHRs in 2014 for the PQRS GPRO (78 FR 43354). Specifically, we proposed to report, no earlier than 2015, performance on the GPRO registry and EHR measures identified below that can also be reported via the GPRO web interface in 2014. By proposing to include on Physician Compare

performance on these measures reported by participants under the GPRO through registries and EHRs, as well as the GPRO web interface, we stated we would continue to provide beneficiaries with a consistent set of measures over time. For registry reporting, publicly reported measures would include:

- Diabetes: Hemoglobin A1c Poor Control.
- Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD).
- Medication Reconciliation.
- Preventive Care and Screening: Influenza Immunization.
- Pneumococcal Vaccination Status for Older Adults.
- Preventive Care and Screening: Breast Cancer Screening.
- Colorectal Cancer Screening.
- Coronary Artery Disease (CAD): Angiotensin-converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy -- Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%).
 - Adult Weight Screening and Follow-Up.
 - Preventive Care and Screening: Screening for Clinical Depression.
 - Coronary Artery Disease (CAD): Lipid Control.
 - Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic.
 - Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention.
 - Hypertension (HTN): Controlling High Blood Pressure.
 - Ischemic Vascular Disease (IVD): Complete Lipid Panel and LDL Control.
 - Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up

Documented.

For EHR reporting, publicly reported measures would include:

- Diabetes: Hemoglobin A1c Poor Control.
- Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD).
- Preventive Care and Screening: Influenza Immunization.

- Pneumococcal Vaccination Status for Older Adults.
- Preventive Care and Screening: Breast Cancer Screening.
- Colorectal Cancer Screening.
- Adult Weight Screening and Follow-Up.
- Coronary Artery Disease (CAD): Lipid Control.
- Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic.
- Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention.
- Hypertension (HTN): Controlling High Blood Pressure.
- Ischemic Vascular Disease (IVD): Complete Lipid Panel and LDL Control.
- Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up

Documented.

Comment: Commenters were opposed to the expansion of public reporting to include measures reported through the registry and EHR reporting options. Some commenters expressed concern that measures reported through different reporting mechanisms may not be comparable. One commenter believes CMS should first validate that the measure specifications are interpreted consistently across groups and across reporting mechanisms. One commenter suggests that it is too soon to have reporting entities publicly post performance data from electronic clinical quality measures (eCQMs) citing that additional work should be done to verify the validity and accuracy of the measure results. Another commenter recommends that CMS include a notation specifying the selected reporting mechanism with a simplified descriptor and accompanying measure set. Such a notation would ensure that patients are made aware of the differences in measure sets across the different reporting mechanisms and it will allow them to know which providers reported on the same measures when comparing performance.

Response: We appreciate the commenters' feedback regarding including measures collected via both registries and EHRs. Though we understand concerns regarding including measures collected via different mechanisms, analyses are being conducted to ensure that these measures are consistently understood and the consistencies and inconsistencies across reporting mechanism are understood and

appropriately addressed for the purposes of publicly reporting these measures. Analyses are also being conducted to ensure that the eCQMs produce valid and accurate results. Only those measures finalized to be published on Physician Compare that are proven to be comparable and most suitable for public reporting will be included on Physician Compare. Because we believe the appropriate steps are being taken to ensure that the proposed measures collected via registries and EHRs are comparable to the web interface measures, such as detailed analyses of the measure specifications across reporting mechanisms, and also valid and reliable, and for the various reasons we discussed previously, we are finalizing the proposal to publish in CY 2015 the measures identified above that are collected via registries and EHRs during 2014, if technically feasible.

CMS will also indicate the mechanism by which these data were collected, as we understand the concerns raised regarding potential differences in measures collected via different reporting mechanism.

Analyses are ongoing to be sure these differences are fully understood.

Consistent with the requirement under section 10331(a)(2) of the Affordable Care Act to make comparable information on patient experience of care measures publicly available, we previously finalized a plan to post performance on patient experience survey-based measures from the Clinician and Group Consumer Assessment of Healthcare Providers and Systems (CG-CAHPS) (77 FR 44804) including the following patient experience of care measures for group practices participating in the PQRS GPRO (77 FR 44964):

- CAHPS: Getting Timely Care, Appointments, and Information.
- CAHPS: How Well Your Doctors Communicate.
- CAHPS: Patients' Rating of Doctor.
- CAHPS: Access to Specialists.
- CAHPS: Health Promotion and Education

These measures capture patients' experiences with clinicians and their staff, and patients' perception of care. We finalized a decision to publicly report performance on these measures on Physician Compare in CY 2014 for data collected for 2013 for group practices with 100 or more eligible

professionals participating in the PQRS GPRO in 2013 and reporting data through the GPRO web interface (77 FR 69166). At least for data reported for 2013, we noted that we would administer and collect patient experience survey data on a sample of the group practices' beneficiaries.

Consistent with the PQRS policy of publicly reporting patient experience measures on Physician Compare starting with data collected for 2013, for ACOs participating in the Shared Savings Program, we will publicly report patient experience data in addition to the measure data reported through the GPRO web interface. Specifically, the patient experience measures that would be reported for ACOs include the CG-CAHPS measures in the Patient/Caregiver Experience domain finalized in the Shared Savings Program final rule (76 FR 67889):

- CAHPS: Getting Timely Care, Appointments, and Information.
- CAHPS: How Well Your Doctors Communicate.
- CAHPS: Patients' Rating of Doctor.
- CAHPS: Access to Specialists.
- CAHPS: Health Promotion and Education.
- CAHPS: Shared Decision Making
- CAHPS: Health Status/Functional Status

For data reported for 2014, we proposed to continue public reporting CG-CAHPS data for PQRS GPRO group practices of 100 or more eligible professionals participating in the GPRO via the web interface and for Shared Savings Program ACOs reporting through the GPRO web interface or other CMS-approved tool or interface (78 FR 43355). Consistent with what we finalized for 2013 under the PQRS GPRO, we stated we would administer and fund the collection of data for these groups. Because we will be administering and collecting the data for these surveys, we did not anticipate public reporting to impose any notable burden on these groups.

We believe these patient surveys are important tools for assessing beneficiary experience of care and outcomes, and under our authority under section 1848(m)(3)(C) of the Act to select the measures for which a group practice must report under the PQRS, we stated that we sought to encourage groups of 25

or more eligible professionals to report CG-CAHPS by proposing to make these measures available for reporting under the PQRS and for the Value Based Payment Modifier. We proposed to publicly report 2014 CG-CAHPS data for any group practice (regardless of size) that voluntarily chooses to report CG-CAHPS; however, we stated that CMS would not fund the surveys for these groups of 2 to 99 eligible professionals. We proposed to publicly report comparable CG-CAHPS data collected by groups of any size collected via a certified CAHPS vendor in CY 2015 (78 FR 43355).

We are dedicated to publicly reporting accurate, valid, and reliable data on Physician Compare and are aware that each group practice is unique in size and scope. We have closely evaluated the available data collection mechanisms, and are confident that CG-CAHPS is a well-tested collection mechanism with strong support from the healthcare community, and that it provides the best opportunity to collect useful and accurate data for the largest number of group practices. We proposed to use only those survey domains that are applicable to group practices or ACOs respectively, and believed that these domains have been well tested, and would therefore provide the best data for the largest number of groups.

We received several comments related to our proposals to publicly report CG-CAHPS measures on Physician Compare. The following is a summary of the comments we received:

Comment: Several commenters support our proposal to continue posting data for groups of 100 or more eligible professionals. Commenters were also generally supportive of the proposal to publish patient experience data for smaller groups; however, some commenters requested clarification on the size of group practice that CMS intends to publicly report, noting that there is conflicting language within the proposed rule regarding groups of 25 or more versus groups "regardless of size." Several of the commenters expressed their disappointment that CMS will not fund the data collection for these smaller groups, noting that it is extremely costly and burdensome on smaller practices to implement CAHPS.

Response: We appreciate the commenters' feedback regarding our proposals to continue publicly reporting CG-CAHPS measures for groups of 100 or more eligible professionals with CY 2014 data and

to begin publicly reporting CG-CAHPS measures for groups of 25 to 99 that voluntarily submit these data to meet PQRS reporting requirements.

We are dedicated to accurate, valid, and reliable public reporting on Physician Compare and are aware that each group practice is unique and that opinions vary across patients. However, as noted, we are confident that CG-CAHPS is a well-tested collection mechanism that produces valid and comparable measures of physician quality.

Per the requirement under section 10331(a)(2) of the Affordable Care Act to make comparable information on patient experience of care measures publicly available, as noted above, and due to the fact that these data are greatly valued by consumers and will assist consumers with making informed healthcare decisions, we are finalizing the proposal to continue to publicly report CG-CAHPS measures for groups of 100 or more eligible professionals who participate in PQRS GPRO, regardless of GPRO submission method, and for Shared Savings Program ACOs reporting through the GPRO web interface or other CMS-approved tool or interface. As in 2013, CMS will support this survey data collection for group practices who participate in PQRS GPRO via the web interface. As patient experience data are required under section 10331(a)(2) of the Affordable Care Act, we are working to ensure that a greater set of measures are available for public reporting to help more group practices find measures that are relevant to them and to ease burden of reporting as some groups may already be collecting CG-CAHPS data under additional domains. For these reasons, we are finalizing that, if technically feasible, for these PQRS GPROs of 100 or more eligible professionals, we will collect data for additional summary survey measures. Specifically, we will collect data for the 12 summary survey measures also being finalized for groups of 25 to 99 for PORS reporting requirements, namely:

- Getting timely care, appointments, and information;
- How well providers Communicate;
- Patient's Rating of Provider;
- Access to Specialists;
- Health Promotion & Education;

- Shared Decision Making;
- Health Status/Functional Status;
- Courteous and Helpful Office Staff;
- Care Coordination;
- Between Visit Communication;
- Helping Your to Take Medication as Directed; and
- Stewardship of Patient Resources.

For the same reasons noted above, for groups of 25 to 99 eligible professionals, we are finalizing the proposal to publicly report on Physician Compare the CG-CAHPS measures collected on the 12 summary survey measures noted above when collected via a certified CAHPS vendor, as technically feasible. We will evaluate the data collected and will only publish those measures deemed suitable for public reporting and that prove to be comparable. As with all measure data reported on Physician Compare, there will be a 30-day preview period where groups can preview their data prior to its publication on the site.

We appreciate the commenter's feedback and the fact that collecting CG-CAHPS data is an expense for smaller group practices. However, if smaller group practices are already collecting these data for internal use, we want to be sure that they are able to have the opportunity to have them published on the site. Therefore, we are finalizing this proposal. CMS will not fund collection of these data for groups of 25 to 99.

<u>Comment</u>: Several commenters opposed the publication of CAHPS measures citing that the measures are not relevant to their particular specialty. They request that CMS allow physicians the flexibility to select the survey instruments and patient satisfaction measures most appropriate for their practices. Many of the commenters recommended CMS use Surgical CAHPS as an optional patient experience of care measure.

Response: We appreciate the commenters' feedback regarding the request for CMS to be flexible in the CAHPS surveys publicly reported to ensure the measures are as relevant as possible to all

specialties. We understand that CG-CAHPS is not the most applicable CAHPS survey for all specialties and service settings represented by groups on Physician Compare. Therefore, we will evaluate the feasibility of including additional CAHPS surveys, such as S-CAHPS, on the site in the future. However, at this time CG-CAHPS provides the best opportunity to reach the largest number of groups with a single survey instrument. CG-CAHPS measures are also being incorporated into the PQRS program, which means that there will more likely be a sufficient number of groups reporting on these measures to allow comparable reporting. For these reasons and because we are working to phase in measures over time, we will not be able to accommodate additional CAHPS measures on Physician Compare at this time.

In the CY 2013 PFS final rule with comment period (77 FR 44804), we indicated our intention to publicly report performance rates on quality measures included in the 2014 PQRS and for individual eligible professionals consistent with the requirements under section 10331 of the Affordable Care Act to provide information about physicians and other eligible professionals who participate in PQRS. We believe that individual-level measure data is important in helping consumers make informed healthcare decisions and that this information should be posted on the site as soon as technically feasible. Therefore, in the proposed rule, we proposed to publicly report comparable data, as noted below, collected for the 2014 PQRS via claims, EHR or registry from individual eligible professionals as early as CY 2015 (78 FR 43355). Specifically, we proposed to post individual measures reported by individual eligible professionals in line with those measures reported by groups through the GPRO web interface. We proposed to include the following measures:

- Diabetes: Hemoglobin A1c Poor Control.
- Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD).
- Medication Reconciliation.
- Preventive Care and Screening: Influenza Immunization.
- Pneumococcal Vaccination Status for Older Adults.
- Preventive Care and Screening: Breast Cancer Screening.
- Colorectal Cancer Screening.

 Coronary Artery Disease (CAD): Angiotensin-converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy -- Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%).

- Adult Weight Screening and Follow-Up.
- Preventive Care and Screening: Screening for Clinical Depression.
- Coronary Artery Disease (CAD): Lipid Control.
- Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic.
- Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention.
- Hypertension (HTN): Controlling High Blood Pressure.
- Ischemic Vascular Disease (IVD): Complete Lipid Panel and LDL Control.
- Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up

Documented.

- Falls: Screening for Fall Risk.
- Diabetes Mellitus: Low Density Lipoprotein (LDL-C) Control.
- Diabetes Mellitus: High Blood Pressure Control.
- Diabetes Mellitus: Hemoglobin A1c Control (<8%).

Comment: Some commenters supported the CMS provision to provide quality information on the individual physician level as soon as feasible. The majority of commenters, however, were opposed to the proposal to report 2014 PQRS individual measure data in CY 2015. Some commenters are concerned that it may not be feasible to accurately represent a physician's performance, because at the individual physician/eligible professional level, there is not always an adequate sample size to make valid comparisons. Other commenters believe that since multiple physicians can be involved in the treatment of a patient, it can be difficult to assess who ultimately is responsible for the care of that patient when evaluating a specific measure. One commenter is concerned that by reporting individual quality measures providers would have an incentive to turn away patients with low health literacy, inadequate financial resources to afford treatment, and ethnic groups traditionally subject to healthcare inequities in order to

improve their process measure performance. Other commenters encourage CMS to limit the publication of measure data to group practices until there is sufficient experience and data to determine what measures, if any, can be reported at the individual level.

Response: We appreciate the commenters' feedback but believe strongly that individual-level measure data are important in helping consumers make informed healthcare decisions, and that this information should be posted on the site as soon as technically feasible. However, we appreciate the concerns raised by other commenters' regarding posting individual measures. We are committed to including only the most accurate, statistically reliable and valid quality of care measure data on Physician Compare when the data are publicly reported. Any data found to be invalid or inaccurate for any reason will not be publicly reported. And, we are confident that the sample size noted will produce comparable data as these measures have been in use in the PQRS program and have undergone significant review. We understand that attribution of care is a concern at the individual physician level, but believe that it can be appropriately determined for the purposes of these measures. We do not believe that collecting data at the individual physician level will cause physicians to turn away patients just as data collection at the hospital and group practice level have not. And, to further help mitigate this concern, we will evaluate risk adjustment to ensure that those physicians that serve a more complex patient population are not unduly penalized. In future years, we will continue to evaluate the available measures and work to ensure that the data on Physician Compare are those best suited for public reporting. We will ensure that these data are collected and presented appropriately, regardless of the mechanism through which they are collected, and that they accurately reflect performance. Only those measures that are reported for the accepted sample size will be publicly reported. And, CMS will work to ensure that the measures are presented in a way that is understood by consumers. We will also evaluate the inclusion of language to help users understand why not all individuals will have quality data reported. Given the importance of making individual eligible professional-level measure data available to the public, CMS is finalizing this proposal to publicly report 2014 PQRS individual measure data in CY 2015 for individual PQRS quality measures listed, if technically feasible.

Additionally, and in support of the HHS-wide Million Hearts Initiative, we proposed to publicly report, no earlier than CY 2015, performance rates on measures in the PQRS Cardiovascular Prevention measures group (see Table 116 at 77 FR 69280) at the individual eligible professional level for data collected in 2014 for the PQRS (see Table 74 of this rule).

<u>Comment</u>: We received three comments regarding the publication of the PQRS Cardiovascular Prevention measures group. Two commenters request that CMS clearly and prominently state that certain physicians or groups are not included in the Million Hearts initiative for numerous reasons. One commenter encouraged CMS to limit public reporting of these measures to the group practice level, citing concerns that these measures if collected via EHRs are new for physicians to report, and thus CMS should allow at least two more years of data collection on these measures before publicly reporting them.

Response: We appreciate the commenters' feedback. We appreciate the concern that reporting via an EHR is new for many physicians and it may take time to become comfortable with the reporting mechanism. However, these measures are not new to PQRS and thus have been previously reported. As noted above concerning individual PQRS measures, we recognize the importance of making individual eligible professional-level measure data available to the public, and find these measures to be specifically relevant to the Physician Compare audience, and are, therefore, finalizing this proposal to publicly report in CY 2015 the individual Cardiovascular Prevention measures in support of the Million Hearts Initiative, if technically feasible. We are evaluating the feasibility of including clarification language to explain why it may not be appropriate for physicians or groups to report these Cardiovascular Prevention measures and will include this language if feasible.

Please note that, during the comment period following the proposed rule, we received comments that were not related to our specific proposals for Physician Compare in the CY 2014 PFS proposed rule. While we appreciate the commenters' feedback and intend to use these comments to better develop Physician Compare, these comments will not be specifically addressed in this CY 2014 PFS final rule with comment period, as they are beyond the scope of this rule. However, we will take these comments into consideration when developing policies and program requirements for future years.

H. Physician Payment, Efficiency, and Quality Improvements – Physician Quality Reporting System

This section contains the final requirements for the Physician Quality Reporting System (PQRS). The PQRS, as set forth in sections 1848(a), (k), and (m) of the Act, is a quality reporting program that provides incentive payments and payment adjustments to eligible professionals and group practices based on whether or not they satisfactorily report data on quality measures for covered professional services furnished during a specified reporting period. The regulation governing the PQRS is located at §414.90. The program requirements for the 2007 through 2014 PQRS incentives and the 2015 PQRS payment adjustment that were previously established, as well as information on the PQRS, including related laws and established requirements, are available at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/index.html. In addition, the 2011 PQRS and eRx Experience Report, which provides information about eligible professional participation in PQRS, is available for download at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/index.html.

We note that eligible professionals in critical access hospitals (CAHs) were previously not able to participate in the PQRS. Due to a change we are making in the manner in which eligible professionals in CAHs are reimbursed by Medicare, it is now feasible for eligible professionals in CAHs to participate in the PQRS.

In the CY 2013 PFS final rule with comment period (77 FR 69170), we finalized certain requirements for the 2013 and 2014 PQRS incentives, as well as 2015 and 2016 PQRS payment adjustments. We also finalized certain requirements for future years, such as the reporting periods for the PQRS payment adjustment, as well as requirements for the various PQRS reporting mechanisms. In the CY 2014 PFS proposed rule, we proposed to change some requirements for the 2014 PQRS incentive and 2016 PQRS payment adjustment, as well as to make changes to the PQRS measure set. Furthermore, we introduced our proposals for a new PQRS reporting option – satisfactory participation in a qualified clinical data registry. This final rule with comment period addresses these proposals and specifically outlines the final requirements for the 2014 PQRS incentive and 2016 PQRS payment adjustment.

Please note that, during the comment period following the proposed rule, we received comments that were not related to our specific proposals for PQRS in the CY 2014 PFS proposed rule. In addition, we also solicited comment on a general plan for future years for PQRS, so that we may continue to consider stakeholder feedback as we develop policies and proposals for the future. While we appreciate the commenters' feedback and intend to use these comments to better develop PQRS, these comments will not be specifically addressed in this CY 2014 PFS final rule with comment period, as they are beyond the scope of this rule. However, we will take these comments into consideration when developing policies and program requirements for future years.

1. Changes to §414.90

As noted previously, the regulation governing the PQRS is located at §414.90. We proposed the following changes and technical corrections to §414.90 (78 FR 43357):

- Under §414.90(b), we proposed to modify the definition of administrative claims to eliminate the words "the proposed" in the phrase "on the proposed PQRS quality measures." We proposed to make this technical change because this language was inadvertently included in the final regulation despite the fact that the quality measures that eligible professionals report under the PQRS were finalized in the CY 2013 PFS final rule with comment period (77 FR 69364).
- We proposed to modify §414.90(f) to include the phrase "for satisfactory reporting" after the title "Use of consensus-based quality measures." We proposed to add the phrase "for satisfactory reporting" so that it is clear that the paragraph refers to satisfactory reporting, not the new standard of satisfactorily participating in a qualified clinical data registry.
- We proposed to modify the paragraph heading of §414.90(g) to add the phrase "satisfactory reporting", so that the title of the paragraph reads "Satisfactory reporting requirements for the incentive payments." We proposed to make this change so that it is clear that the paragraph refers to satisfactory reporting, not the new standard of satisfactorily participating in a qualified clinical data registry. Please note that, due to additional changes we are making to §414.90, paragraph §414.90(g) is now designated as §414.90(h).

• We proposed to modify the paragraph heading of §414.90(h) to add the phrase "satisfactory reporting", so that the title of the paragraph reads "Satisfactory reporting requirements for the incentive payments." We proposed to make this change so that it is clear that the paragraph refers to satisfactory reporting, not the new standard of satisfactorily participating in a qualified clinical data registry. Please note that, due to additional changes we are making to §414.90, paragraph §414.90(g) is now designated as §414.90(j).

• We proposed to delete paragraph §414.90(i)(4), because §414.90(i)(4) list requirements that are identical to §414.90(i)(3), and therefore, redundant.

In addition, we considered further revising the regulation at §414.90 to list all the specific satisfactory reporting requirements for the 2014 PQRS incentive and 2016 PQRS payment adjustment, so that the different reporting requirements are specified in the regulation. We are making this change. Therefore, we are adding newly redesignated paragraphs §414.90(h)(3), §414.90(h)(5), §414.90(j)(3), and §414.90(j)(5) to list all the specific satisfactory reporting requirements for the 2014 PQRS incentive and 2016 PQRS payment adjustment.

We solicited but received no public comment on these proposals. Therefore, we are finalizing these proposed technical changes.

In the course of revising the regulation text to address the technical changes and final policies we are adopting in this final rule, we discovered a number of drafting errors and technical issues. In addition to the technical changes and corrections noted above, as well as the substantive changes discussed in the sections that follow, we also are modifying §414.90 as follows:

- Changing references to the Physician Quality Reporting System to its acronym, the PQRS, throughout §414.90 to shorten the regulation. This technical change is consistent with the references to the program we have made in the proposed rule.
- Deleting the phrase "as defined in paragraph (b) of this section" when referring to group practices throughout §414.90, because it is redundant to refer back to the definition of a group practice.

• Amending §414.90(d) to indicate that, in lieu of satisfactory reporting, an eligible professional may also satisfactorily participate in a qualified clinical data registry in 2014.

- Changing the title of §414.90(f) currently titled "Use of consensus-based quality measures" to "Use of appropriate and consensus-based quality measures for satisfactory reporting" to indicate criteria for measure selection for measures available under the group practice reporting option (GPRO).
- Combining §414.90(f)(1) and §414.90(f)(2) as measures under the PQRS may fit either of these two criteria.
- Adding paragraph (n) entitled "Limitations on review." This "limitations on review" paragraph, previously designated in §414.90 as paragraph (k) was inadvertently deleted from §414.90 in the CY 2013 PFS final rule with comment period. In lieu of this section, a duplicate paragraph (k) describing the PQRS informal review process was inserted. We are therefore deleting the duplicate informal review paragraph (k) and restoring paragraph (n).

In addition, the previously established paragraph entitled "limitations on review" included the following paragraph at §414.90(k)(2): "The determination of the payment limitation." This provision pertains to the Electronic Prescribing (eRx) Incentive Program and is irrelevant to the PQRS. Therefore, we are deleting that reference. Moreover, to be consistent section 1848(m)(5)(E) of the Act, we are adding to the "limitations on review" paragraph the following: "The determination of satisfactory reporting.", which was inadvertently left out (presumably because we inadvertently listed an element of the eRx Incentive Program instead, as noted above). This technical change also necessary so that newly designated paragraph (1) will be consistent with section 1848(m)(5)(E) of the Act.

Although we did not include these technical changes in the proposed rule, we believe it is unnecessary to undergo notice and comment rulemaking given that these changes are purely technical in nature and correct errors inadvertently made previously to the regulation, and do not substantively change the regulation. Finally, we note that we have made further structural and conforming changes to the regulation (for example, adding, deleting, and redesignating paragraphs) consistent with the changes and final policies we are adopting in this final rule.

2. Participation as a Group Practice in the Group Practice Reporting Option (GPRO) – Changes to the Self-nomination, or Registration, Requirement for Group Practices to be Selected to Participate in the GPRO

In the CY 2013 PFS final rule with comment period (77 FR 69172), we finalized requirements regarding the self-nomination process group practices must follow to participate in the PQRS GPRO. In the CY 2014 PFS final rule with comment period, we proposed (78 FR 43357) to make the changes to those requirements for group practices to self-nominate. First, we proposed to change the deadline of October 15 of the year in which the reporting period occurs for group practices to submit a self-nomination statement, or register, to participate in the PQRS GPRO. Starting with reporting periods occurring in 2014, we proposed (78 FR 43357) to change this deadline to September 30 of the year in which the reporting period occurs (that is, September 30, 2014, for reporting periods occurring in 2014).

We solicited and received the following public comments regarding our proposal to change the deadline that a group practice must register to participate in the GPRO:

Comment: Several commenters did not support our proposal to change the deadline that a group practice must register to participate in the GPRO by September 30 of the year in which the reporting period occurs (that is September 30, 2014 for reporting periods occurring in 2014) suggesting that it is important that group practices are allowed more time to decide on whether they should participate in PQRS as a group practice or as individuals. The commenters felt that the later registration deadline of October 15 of the year in which the reporting period occurs or later allows more time for group practices to make a more informed decision, as well as account for changes in the composition of the group practice, such as changes in a group practice's Taxpayer Identification Number (TIN).

Response: While we understand the commenters' concerns and proposed a deadline of September 30 of the year in which the reporting period occurs, we noted in the proposed rule (78 FR 43357) that CMS needs additional time to identify group practices wishing to participate in the GPRO for a year in order to allow for more time to populate the GPRO web interface for those group practices that select the GPRO web interface reporting mechanism. Unfortunately,we cannot finalize a deadline later than

September 30. Despite the comments we received requesting a later deadline, based on the reasons previously mentioned, we are requiring that group practices register to participate in the GPRO by September 30 of the year in which the reporting period occurs (that is September 30, 2014 for reporting periods occurring in 2014), as proposed.

We note that we received comments related to proposals for the Value-based Payment Modifier (discussed in section III.K. of this final rule with comment period) requesting more timely feedback on group practice reporting, particularly information related Clinician Group Consumer Assessment of Healthcare Providers and Systems (CG CAHPS) survey. Since the performance of a group practice in the Value-based Payment Modifier is determined, in part, by a group practice's participation in the PQRS, to provide timelier feedback to these group practices, in order for eligible professionals to be able to receive feedback on CG CAHPS data and assess by the Value-based Payment Modifier, it would be necessary for CMS to identify which groups will be participating in the PQRS under the GPRO earlier than September 30 of the year in which the reporting period occurs. Therefore, to respond to the commenters concerns to provide timelier feedback on performance on CG CAHPS in the future, we anticipate proposing an earlier deadline for group practices to register to participate in the GPRO in future years.

Second, we proposed (78 FR 43357) that group practices comprised of 25 or more individual eligible professionals that wish to report the CG CAHPS survey measures (which are discussed later in this section) would be required via the web to elect to report the CG CAHPS survey measures. We solicited and received no comments on this proposal. Therefore, we are finalizing our proposal to require group practices of 25 or more individual eligible professionals that wish to report the CG CAHPS survey measures to indicate their intent to do so upon registration.

Furthermore, we proposed (78 FR 43357) that the website that a group practice would use to elect to report the CG CAHPS survey measures would be the same website used by group practices to register to participate in the PQRS GPRO. We believe that providing a single website whereby group practices may make multiple elections (such as submitting the self-nomination statement to register to participate in

the PQRS GPRO and be evaluated for the PQRS GPRO using CG CAHPS measures would be desirable for group practices.

We solicited and received the following public comments on this proposal:

Comment: Several commenters supported our proposal to use a single website to register to participate in the PQRS GPRO. The commenters believed that using a single website for functions relating to different CMS programs furthers CMS' goal of alignment, as well as aids in the group practice's management in participation in CMS' various quality reporting programs. Commenters urged CMS to further align and create a single website that will manage participation in the PQRS, EHR Incentive Program, and the Value-based Payment Modifier.

Response: We appreciate the commenters' feedback and the support for this proposal. For the reasons stated above, we are finalizing our proposal to use a single website whereby a group practice of 25 or more individual eligible professionals may register to participate in the PQRS GPRO and elect to be evaluated for the PQRS GPRO by reporting CG CAHPS measures.

3. Requirements for the PQRS Reporting Mechanisms

The PQRS includes the following reporting mechanisms: claims; registry; EHR (including direct EHR products and EHR data submission vendor products); administrative claims; and the GPRO web-interface. Under the existing PQRS regulation, section 414.90(g) and (h) govern which reporting mechanisms are available for use by individuals and group practices for the PQRS incentive and payment adjustment. This section contains the changes we are finalizing for these PQRS reporting mechanisms. In addition, this section contains the final requirements for two new PQRS reporting mechanisms – a new certified survey vendor reporting mechanism for purposes of reporting CG CAHPS measures and a qualified clinical data registry reporting mechanism under the new PQRS "satisfactory participation" reporting option.

a. Registry-based Reporting Mechanism

In the CY 2013 PFS final rule with comment period, we finalized the following requirement for registries to become qualified to participate in PQRS for 2013 and beyond: Be able to collect all needed

data elements and transmit to CMS the data at the TIN/NPI level for at least 3 measures (77 FR 69180). In the proposed rule, since we proposed (78 FR 43358) to increase the number of measures eligible professionals would be required to report for the 2014 PQRS incentive from 3 to 9 measures covering at least 3 of the National Quality Strategy (NQS) domains, we proposed (78 FR 43358) to change this registry requirement as follows: A qualified registry must be able to collect all needed data elements and transmit to CMS the data at the TIN/NPI level for at least 9 measures covering at least 3 of the NQS domains. We solicited but received no public comment on this proposal. Therefore, as we describe in detail below, since we are finalizing our proposal to increase the number of measures eligible professionals would be required to report for the 2014 PQRS incentive via qualified registry from 3 to 9 measures covering at least 3 of the NQS domains, we are finalizing this proposal.

b. Certified Survey Vendors

We proposed (78 FR 43358) to allow group practices composed of 25 or more eligible professionals to report CG CAHPS survey measures. The data collected on these CAHPS survey measures would not be transmitted to CMS via the previously established PQRS group practice reporting mechanisms (registry, EHR, or GPRO web interface). Rather, the data must be transmitted through a survey vendor. Therefore, to allow for the survey vendor to transmit survey measures data to CMS, we proposed to modify §414.90(b), §414.90(g)(3), and §414.90(h)(3) to propose a new reporting mechanism – the certified survey vendor (78 FR 43358). We solicited and received the following public comment on this proposal:

<u>Comment</u>: Several commenters supported our proposal to allow group practices of 25-99 eligible professionals to report the CG CAHPS survey measures and therefore generally supported our proposal to create a new reporting mechanism – the CMS-certified survey vendor – to administer the CG CAHPS survey measures.

Response: We appreciate the commenters' feedback and are finalizing the creation of a new reporting mechanism, the CMS-certified survey vendor, to report the CG CAHPS survey measures. Therefore, we are finalizing our proposal to modify §414.90(b), newly designated §414.90(h)(3), and

newly designated §414.90(j)(3) to indicate a group practice's ability to use a new reporting mechanism – the CMS-certified survey vendor.

<u>Comment</u>: Although commenters supported our proposal to allow group practices of 25-99 eligible professionals to report the CG CAHPS survey measures, the commenters opposed our proposal to require these group practices to report the CG CAHPS survey measures via a CMS-certified survey vendor. The commenters believed that group practices should have the flexibility to report CG CAHPS measures in any way the group practices choose, not solely through a CMS-certified survey vendor.

Response: While we appreciate the commenters' concern to allow flexibility in allowing group practices to report the CG CAHPS measures, we must create parameters surrounding how the CG CAHPS survey measures would be reported to CMS. Similar to our other reporting mechanisms, we believe it is also important to ensure that vendors are able to test submission of CG CAHPS measures data prior to the submission period. We believe that requiring that the vendor be certified by CMS to submit CG CAHPS survey measures data furthers this goal. Therefore, we are requiring that group practices use a CMS-certified survey vendor if the group practice wishes to report CG CAHPS survey measures data for purposes of the PQRS.

In addition, §414.90(g)(3), and §414.90(h)(3) currently requires group practices to use only one mechanism to meet the requirements for satisfactory reporting (that is, CMS will not combine data submitted under multiple reporting mechanism to determine if the requirements for satisfactory reporting are met). However, for the proposed certified survey vendor option, we also proposed that a group practice choosing to report CG CAHPS survey measures would be required to select an additional reporting mechanism to meet the requirements for satisfactory reporting for both the 2014 PQRS incentive and the 2016 PQRS payment adjustment (78 FR 43358). Therefore, we proposed to modify §414.90(g)(3), and §414.90(h)(3) to indicate that groups selecting to use the certified survey vendor would be the exception to this requirement. We received no public comment on this proposal and therefore, for the reasons we previously stated, are finalizing our proposal to modify newly designated §414.90(h)(3), and §414.90(j)(3) to indicate that groups selecting to use the certified survey vendor would

be required to meet the criteria for satisfactory reporting using an additional reporting mechanism to report additional measures.

For purposes of PQRS, we proposed to modify §414.90(b) to define a certified survey vendor as a vendor that is certified by CMS for a particular program year to transmit survey measures data to CMS (78 FR 43358). To obtain CMS certification, we proposed that vendors would be required to undergo training, meet CMS standards on how to administer the survey, and submit a quality assurance plan. CMS would provide the identified vendor with an appropriate sample frame of beneficiaries from the group. The vendor would also be required to administer the survey according to established protocols to ensure valid and reliable results. Survey vendors would be supplied with mail and telephone versions of the survey in electronic form, and text for beneficiary pre-notification and cover letters. Surveys can be administered in English, Spanish, Cantonese, Mandarin, Korean, Russian and/or Vietnamese. Vendors would be required to use appropriate quality control, encryption, security and backup procedures to maintain survey response data. The data would then be securely sent back to CMS for scoring and/or validation. To ensure that a vendor possesses the ability to transmit survey measures data for a particular program year, we proposed to require survey vendors to undergo this certification process for each year in which the vendor seeks to transmit survey measures data to CMS. We solicited and received no public comment on these proposals. Therefore, we are finalizing these proposals, as well as the proposed change at §414.90(b).

4. Changes to the Criteria for the Satisfactory Reporting for Individual Eligible Professionals for the 2014 PQRS Incentive – Individual Quality Measures Submitted via Claims and Registries and Measures Groups Submitted via Claims

For 2014, in accordance with §414.90(c)(3), eligible professionals that satisfactorily report data on PQRS quality measures are eligible to receive an incentive equal to 0.5 percent of the total estimated Medicare Part B allowed charges for all covered professional services furnished by the eligible professional or group practice during the applicable reporting period. Individual eligible professionals may currently report PQRS quality measures data to meet the criteria for satisfactory reporting for the

2014 PQRS incentive via the claims, registry, and EHR-based reporting mechanisms. This section contains our final changes to the criteria for satisfactory reporting of individual quality measures via claims and registries by individual eligible professionals for the 2014 PQRS incentive. Please note that we did not propose to modify and are therefore not modifying the criteria for satisfactory reporting of individual quality measures via EHR that were established in the CY 2013 PFS final rule with comment period (see Table 91, 77 FR 69194). For ease of reference, these criteria for satisfactory reporting of individual quality measures via EHR for the 2014 PQRS incentive are also identified again in Table 47 of this final rule with comment period.

a. Proposed Changes to the Criterion for Satisfactory Reporting of Individual Quality Measures via
 Claims for Individual Eligible Professionals for the 2014 PQRS Incentive

In the CY 2013 PFS final rule with comment period (see Table 91, 77 FR 69194), to maintain the reporting criterion with which individual eligible professionals are familiar, we finalized the same satisfactory reporting criterion for the submission of individual quality measures via claims that we finalized in previous years: For the 12-month reporting period for the 2014 PQRS incentive, report at least 3 measures, OR, if less than 3 measures apply to the eligible professional, report 1—2 measures, AND report each measure for at least 50 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted. For an eligible professional who reports fewer than 3 measures via the claims-based reporting mechanism, the eligible professional would be subject to the Measures Applicability Validation (MAV) process, which would allow us to determine whether an eligible professional should have reported quality data codes for additional measures (77 FR 69188).

Under our authority to revise the criteria for satisfactory reporting for the 2014 PQRS incentive under section 1848(m)(3)(d) of the Act, we proposed (78 FR 43358) to change the criterion for the satisfactory reporting of individual, claims-based measures by individual eligible professionals for the 2014 PQRS incentive as follows: For the 12-month reporting period for the 2014 PQRS incentive, report at least 9 measures, covering at least 3 of the NQS domains, OR, if less than 9 measures apply to the

eligible professional, report 1—8 measures, AND report each measure for at least 50 percent of the Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted. For an eligible professional who reports fewer than 9 measures covering less than 3 NQS domains via the claims-based reporting mechanism, the eligible professional would be subject to the MAV process, which would allow us to determine whether an eligible professional should have reported quality data codes for additional measures. We proposed to allow eligible professionals to report fewer than 9 measures so that eligible professionals who do not have at least 9 claims-based PQRS measures applicable to his/her practice would still have an opportunity to still meet the criteria for satisfactory reporting for the 2014 PQRS incentive by reporting on as many applicable claims-based measures as the eligible professionals can report.

We solicited public comment on the proposed change to the criterion for the satisfactory reporting of individual quality measures via claims for individual eligible professionals for the 2014 PQRS incentive and received the following comments:

<u>Comment</u>: Several commenters supported our proposal to increase the number of measures to be reported via claims, as requiring an eligible professional to report on more measures would better capture the quality of care provided by an eligible professional.

Response: We appreciate the commenters' feedback and, based on the supportive comments received and for the reasons mentioned above and in the proposed rule (78 FR 43358), are finalizing this proposed criterion.

<u>Comment</u>: While several commenters generally supported our proposal to increase the number of measures and NQS domains to be reported via claims, the commenters urged CMS to take a more gradual approach to increasing the number of measures that must be reported via claims. These commenters suggested requiring the reporting of either 4 measures covering at least 1 NQS domain, 5 measures covering at least 2 NQS domains, or 6 measures covering at least 2 NQS domains.

Response: We appreciate the commenters' support for our desire to increase the number of measures to be reported via claims, as well as their alternative suggestions on how to increase the number

of measures to be reported via claims. As we explain in more detail when we discuss our final requirements for the 2016 PQRS payment adjustment, we agree that a more gradual increase in the number of measures to be reported may be necessary for purposes of meeting the criteria for satisfactory reporting for the PQRS payment adjustments. However, since the PQRS program has provided incentives for satisfactory reporting since 2007, we believe it is appropriate to increase the number of measures to be reported via claims from 3 measures covering 1 NQS domain to 9 measures covering 3 NQS domains for the 2014 PQRS incentive. We believe 6 years is enough time for eligible professionals to familiarize themselves with the reporting options for satisfactory reporting under the PORS. Additionally, we point out that we will be using a MAV process for individual eligible professionals who report less than 9 measures via claims, given that an eligible professional who does not have at least 9 measures covering less than 3 NOS domains applicable to his/her practice may report the number of measures applicable to the eligible profession (i.e., fewer than 9 measures) to attempt to meet the criteria for satisfactory reporting for the 2014 PORS incentive via claims. Through the MAV process, we will determine whether the eligible professional reported the measures applicable to the eligible professional. For the commenters' suggested alternative criteria, while we understand the commenters' concerns, we believe our interest in aligning the satisfactory reporting criteria of individual measures via claims with the satisfactory reporting criteria of individual measures via EHR for the 2014 PQRS incentive outweighs the need for such a gradual increase in the number of measures required to be reported via claims.

<u>Comment</u>: One commenter stated that we should not align the PQRS reporting criteria for reporting mechanisms other than the EHR-based reporting mechanisms with the reporting criteria for the EHR Incentive Program, as the objectives for the two programs are different.

Response: We respectfully disagree. Although the standards and criteria for which the PQRS and EHR Incentive Program provide incentives and relieve eligible professionals from payment adjustments are different, the two programs are both dedicated to the promotion of EHR technology and the collection of meaningful and quality data.

Comment: The majority of commenters opposed our proposal to increase the number of measures to be reported via claims from 3 measures covering 1 NQS domain to 9 measures covering 3 NQS domains. Several of these commenters generally opposed any proposal that would increase the number of measures to be reported via claims from 3 measures covering 1 NQS domain. Some of these commenters noted that they have been successful at meeting the criteria for satisfactory reporting in the PORS via claims in the past, and increasing the number of measures to be reported via claims would make it more difficult for these eligible professionals to meet the criteria for satisfactory reporting for the 2014 PORS incentive. Other commenters urged CMS not to increase the criteria for satisfactory reporting until participation in PQRS increases, as the commenters feared that increasing the criteria for satisfactory reporting in PQRS would discourage eligible professionals from participating in the PQRS. Still some of the commenters opposing this proposal noted that certain eligible professionals did not have 9 measures covering 3 NQS domains for which to report. These commenters stressed that being able to report at least 9 measures covering 3 NOS domains via claims for the 2014 PORS incentive would be particularly difficult since we are proposing to eliminate the claims-based reporting mechanism as an option to report certain PQRS measures. Some of these commenters also expressed concern that certain practices having a limited number of applicable measures will not have applicable measures covering at least 3 NQS domains.

Response: We understand the commenters' concerns. As we noted above and in the proposed rule (78 FR 43358), we believe that we have provided eligible professionals with enough time to familiarize themselves with the reporting options for satisfactory reporting under the PQRS, particularly for the PQRS incentives.

For the commenters who urge us not to increase the satisfactory reporting criteria for the PQRS until participation in PQRS increases, we understand that, as discussed in this final rule below and in the 2011 PQRS and eRx Reporting Experience, participation in the PQRS has fluctuated around 25 percent among those eligible to participate in the PQRS. Indeed, it is one of our major goals to increase participation in the PQRS. While increasing the satisfactory reporting threshold for the 2014 PQRS

incentive may deter or discourage eligible professionals from participating, we do not believe increased threshold we are finalizing will significantly deter eligible professionals from participating in the PQRS primarily given that the 2016 PQRS payment adjustment is applicable, and the reporting periods of the 2016 PQRS payment adjustment run concurrently with the reporting periods for the 2014 PQRS incentive. Since eligible professionals are required to meet the criteria for satisfactory reporting for the 2016 PQRS payment adjustment to avoid a reduction to the physician fee schedule payments, we believe these eligible professionals will also attempt to report for the 2014 PQRS incentive regardless of whether we increase the measure threshold from 3 measures covering 1 NOS domain to 9 measures covering 3 NQS domains. For the commenters' concerns on not having at least 9 PQRS measures covering 3 NQS domains for which to report via claims, particularly since we proposed to eliminate the claims-based reporting mechanism as a mechanism for which to report certain measures, we note that our proposal, which we are finalizing, allows eligible professionals to report 1-8 measures that are applicable, if the eligible professional does not have 9 applicable measures to report. If an eligible professional does not have 9 applicable measures to report, the eligible professional must report on as many measures covering as many domains as are applicable to his/her practice. For example, if an eligible professional only has 7 measures covering 2 NQS domains applicable to his/her practice, he/she must report all 7 measures covering 2 NOS domains in order to meet the criteria for satisfactory reporting for the 2014 PQRS incentive. It would not be sufficient for the eligible professional to report on, for example, 6 measures covering 2 NQS domains or 6 measures covering 1 NQS domain.

Given this aspect of the satisfactory reporting criterion, which would address these commenters concerns, we believe it is appropriate to finalize this satisfactory reporting criterion and the general increase in measures to up to 9. Also, we note that for eligible professionals who report 1-8 measures, we will use the MAV process. The current claims MAV process for the 2013 PQRS incentive is only triggered when an eligible professional reports on 1 or 2 measures covering 1 NQS domain via claims since, to meet the criteria for satisfactory reporting for the 2013 PQRS incentive, an eligible professional is only required to report on 3 measures covering 1 NQS domain (77 FR 69189). Since we are increasing

the satisfactory reporting threshold from 3 measures covering 1 NQS domain to 9 measures covering at least 3 NQS domains, we are amending the 2013 MAV process for claims so that the 2014 claims MAV process will be triggered when an eligible professional reports on less than 9 measures covering at least 3 NQS domains. Therefore, the MAV process will be triggered when an eligible professional reports on either less than 9 measures or measures covering less than 3 NQS domains. If an eligible professional reports on less than 9 measures, the MAV process will also check to determine whether the eligible professional is reporting of the maximum amount of NQS domains (up to 3 NQS domains) applicable.

For example, if an eligible professional reports on 8 measures covering 2 NQS domains, the MAV process will be triggered to determine whether an eligible professional could have reported on at least 9 measures and covering at least 3 NQS domains. Likewise, if an eligible professional reports on 9 measures covering 2 domains, the MAV process will be triggered to determine whether an eligible professional could have reported on measures covering an additional domain. As in previous years, the MAV process will use a two-part test – (1) a "clinical relation" test, and (2) a "minimum threshold" test – to determine whether an eligible professional could have reported on more measures.

To get a better sense of how the 2014 MAV process for claims will be implemented by CMS, please see our documentation explaining the current 2013 MAV process for claims. A description of the current claims MAV process is available at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-
Assessment-

<u>Instruments/PQRS/Downloads/2013_PQRS_MeasureApplicabilityValidation_Docs_030413.zip.</u> Please note that we will post a guidance document on the 2014 claims MAV process, which will include a list of the measure clusters that are used for the "minimum threshold" test, prior to January 1, 2014 (the start of the 2014 reporting periods).

In summary, we are adding paragraph §414.90(h)(3) to specify that, to meet the criterion for satisfactory reporting of individual, claims-based measures by individual eligible professionals for the 2014 PQRS incentive an eligible professional must, for the 12-month reporting period for the 2014 PQRS incentive, report at least 9 measures covering at least 3 NQS domains, OR, if less than 9 measures

covering at least 3 NQS domains apply to the eligible professional, report 1—8 measures covering 1-3 NQS domains as applicable, AND report each measure for at least 50 percent of the Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted. For an eligible professional who reports fewer than 9 measures covering less than 3 NQS domains, the eligible professional would be subject to the MAV process, which would allow us to determine whether an eligible professional should have reported quality data codes for additional measures and/or covering additional NQS domains.

b. Changes to the Criterion for Satisfactory Reporting of Individual Quality Measures via Registry for Individual Eligible Professionals for the 2014 PQRS Incentive

In the CY 2013 PFS final rule with comment period, to maintain reporting criterion with which individual eligible professionals are familiar, we finalized the same satisfactory reporting criterion for individual eligible professionals to report individual quality measures via registry that we finalized in previous years: For the 12-month reporting period for the 2014 PQRS incentive, report at least 3 measures AND report each measure for at least 80 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted (77 FR 69189). In the proposed rule, we proposed (78 FR 43359) to change this reporting criterion for individual eligible professionals reporting via registry for the 2014 PQRS incentive to the following: For the 12-month reporting period for the 2014 PQRS incentive, report at least 9 measures covering at least 3 of the NQS domains AND report each measure for at least 50 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted (78 FR 43359).

We solicited and received the following public comments on the proposed changes to the criterion for the satisfactory reporting of individual quality measures via registry for individual eligible professionals for the 2014 PQRS incentive:

<u>Comment</u>: The majority of commenters supported our proposal to decrease the percentage of patients that must be reported via registry from 80 percent to 50 percent. The commenters supported our proposal specifically because it aligns with the option to report individual measures via the claims-based reporting mechanism.

Response: We appreciate the commenters' feedback and, based on the support received and for the reasons stated in the proposed rule (78 FR 43359), we are finalizing this proposal with regard to the percent threshold. Therefore, to meet the criteria for satisfactory reporting for the 2014 PQRS incentive, an eligible professional reporting individual quality measures via registry will be required to report each measure for at least 50 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies.

<u>Comment</u>: One commenter stated that we should not align the PQRS reporting criteria for reporting mechanisms other than the EHR-based reporting mechanisms with the reporting criteria for the EHR Incentive Program, as the objectives for the two programs are different.

Response: We respectfully disagree. Although the standards and criteria for which the PQRS and EHR Incentive Program provide incentives and relieve eligible professionals from payment adjustments are different, the two programs are both dedicated to the promotion of EHR technology and the collection of quality data.

Comment: The majority of commenters opposed our proposal to increase the number of measures to be reported via registry from 3 measures covering 1 NQS domain to 9 measures covering 3 NQS domains. Several of these commenters generally opposed any proposal that would increase the number of measures to be reported via registry from 3 measures covering 1 NQS domain. Some of these commenters noted that they have been successful at meeting the criteria for satisfactory reporting in the PQRS via registry in the past, and increasing the number of measures to be reported via registry would make it more difficult for these eligible professionals to meet the criteria for satisfactory reporting for the 2014 PQRS incentive. Other commenters urged CMS not to increase the criteria for satisfactory reporting until participation in PQRS increases, as the commenters feared that increasing the criteria for satisfactory

reporting in PQRS would discourage eligible professionals from participating in the PQRS. Still some of these commenters opposing this proposal noted that certain eligible professionals did not have 9 measures covering 3 NQS domains for which to report.

Response: We understand the commenters' concerns about increasing the number of measures to be reported via registry from 3 measures covering 1 NQS domain to 9 measures covering 3 NQS domains. However, we believe it is important to collect data that provides a broad picture of the quality of care provided by an eligible professional, specifically since, as discussed in section K of this final rule with comment period, the Value-based Payment Modifier will use participation in PQRS to determine upward, downward, and neutral adjustments based on physician performance. We also believe it is important to cover 3 NQS domains. As we noted above and in the proposed rule (78 FR 43359), we believe that we have provided eligible professionals with enough time to familiarize themselves with the reporting options for satisfactory reporting under the PQRS, particularly for the PQRS incentives, and thefore, we find this increase appropriate.

For the commenters who urge us not to raise the satisfactory reporting criteria for the PQRS until participation in PQRS increases, we understand that, as discussed in this final rule below and in the 2011 PQRS and eRx Reporting Experience, participation in the PQRS has fluctuated around 25 percent among those eligible to participate in the PQRS. Indeed, it is one of our major goals to increase participation in the PQRS. While increasing the satisfactory reporting threshold for the 2014 PQRS incentive may deter or discourage some eligible professionals from participating, we believe that this increase to the satisfactory reporting threshold will not significantly deter eligible professionals from participating in the PQRS. In particular, eligible professionals will be required to report PQRS quality measures data in 2014 to meet the criteria for satisfactory reporting for the 2016 PQRS payment adjustment, which we believe will be an incentive for participation. In addition, we note the reporting periods for the 2014 PQRS incentive and 2016 PQRS payment adjustment run concurrently. Since eligible professionals will already be required to meet the criteria for satisfactory reporting for the 2016 PQRS payment adjustment, we believe these eligible professionals will also attempt to report for the 2014 PQRS incentive regardless of

whether we increase the measure threshold from 3 measures covering 1 NQS domain to 9 measures covering 3 NQS domains.

For the commenters' concerns about not having at least 9 PQRS measures covering 3 NQS domains for which to report via registry, we understand the commenters concerns. While we are still finalizing our proposal to increase the number of individual measures required to be reported via registry to meet the criteria for satisfactory reporting for the 2014 PQRS incentive to 9 measures covering 3 domains, to address the concern for those eligible professionals who fear they do not have 9 individual PORS measures and/or measures covering at least 3 NOS domains applicable to their practice, we are modifying our proposal to allow eligible professionals to report fewer measures so that eligible professionals who do not have at least 9 PQRS measures applicable to their practice can still meet this criteria for satisfactory reporting for the 2014 PQRS incentive by reporting 1-8 measures covering for which there is Medicare patient data. If an eligible professional does not have 9 applicable measures to report, the eligible professional must report on as many measures covering as many NOS domains (up to 3 NQS domains) as are applicable to his/her practice. For example, if an eligible professional only has 7 measures covering 2 NQS domains applicable to his/her practice, he/she must report all 7 measures covering 2 NQS domains in order to meet the criteria for satisfactory reporting for the 2014 PQRS incentive. It would not be sufficient for the eligible professional to report on, for example, 6 measures covering 1 NOS domains.

Given that change, we will analyze eligible professionals who report 1-8 measures using a Measures Application Validity (MAV) process (similar to the claims MAV process we discussed above) to ensure whether the eligible professionals could have reported on the applicable measures. This is consistent with our practice for applying this process to the claims-based reporting option for eligible professionals to report individual measures.

Specifically, if fewer than 9 measures and/or measures covering fewer than 3 NQS domains apply to the eligible professional, an eligible professional must report 1-8 measures covering 1-3 NQS domains for which there is Medicare patient data. The MAV process will be triggered when an eligible

professional reports on less than 9 measures. For example, if an eligible professional reports on 8 measures covering 3 NQS domains, the MAV process will be triggered to determine whether an eligible professional could have reported on an additional measure to report on a total of 9 measures covering 3 NQS domains.

The 2014 registry MAV process that will determine whether an eligible professional could have reported on more measures and/covering more NQS domains will be similar to the "clinical relation" test used in the 2013 claims MAV process. To get a better sense of how the 2014 registry MAV process will be implemented by CMS, a description of the "clinical relation" test in the current 2013 claims MAV process is available at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-
Instruments/PQRS/Downloads/2013_PQRS_MeasureApplicabilityValidation_Docs_030413.zip. Please note that we will post a guidance document on the 2014 registry MAV process, which will include a list of the measure clusters that are used for the "clinical relation" test, prior to January 1, 2014 (the start of the 2014 reporting periods).

We believe the changes we are finalizing will address commenters concerns, while still maintaining our general goal of increasing the measures reported to 9 measures covering 3 NQS domains. This also will increase the likelihood that more eligible professionals will be able to take advantage of this reporting option.

<u>Comment</u>: Several commenters supported our proposal to increase the number of measures to be reported via registry, as requiring an eligible professional to report on more measures would better capture the quality of care provided by an eligible professional.

Response: We appreciate the commenter's feedback with regard to the increase in measures. However, as discussed below, we are making a change in the final rule with regard to the applicable measures that must be reported under this satisfactory reporting criterion.

<u>Comment</u>: While several commenters generally supported our proposal to increase the number of measures to be reported via registry, the commenters urged CMS to provide a more gradual approach to increasing the number of measures that must be reported via registry. These commenters suggested

requiring the reporting of either 4 measures covering at least 1 NQS domain, 5 measures covering at least 2 NQS domains, or 6 measures covering at least 2 NQS domains.

Response: We appreciate the commenters' support for our desire to increase the number of measures to be reported via registry, as well as their alternative suggestions on how to increase the number of measures to be reported via registry. While we agree that a more gradual increase in the number of measures to be reported may be necessary for purposes of meeting the criteria for satisfactory reporting for the 2016 PORS payment adjustment, since 2016 would only be the second year in which an eligible professional could be subject to a PQRS payment adjustment, we do not believe this reasoning applies to satisfactory reporting criteria related to the 2014 PQRS incentive. For the 2014 PQRS incentive, as we stated with claims-based reporting, the PQRS program has provided incentives for satisfactory reporting since 2007, and we believe 6 years is a reasonable amount of time to allow eligible professionals to become familiar with the requirements for earning a PQRS incentive. In fact, eligible professionals have traditionally been successful in meeting the criteria for satisfactory reporting using the registry-based reporting mechanism. According to the 2011 PQRS and eRx Experience Report, 88 percent of eligible professionals reporting individual measures using the registry-based reporting mechanism in 2011 met the criteria for satisfactory reporting for the 2011 PQRS incentive. Therefore, our concerns on gradually phasing in an increased reporting threshold for the 2016 PQRS payment adjustment does not apply here with the 2014 PQRS incentive. We believe it is appropriate to increase the number of measures to be reported via registry from 3 measures covering 1 NQS domain to 9 measures covering 3 NQS domains for the 2014 PQRS incentive.

For the commenters' suggested alternative criteria, while we understand the commenters' concerns, we believe our interest in aligning the satisfactory reporting criteria of individual measures via registry with the satisfactory reporting criteria of individual measures via EHR for the 2014 PQRS incentive outweighs the need for a gradual increase in the number of measures required to be reported via registry.

For the reasons stated above, we are finalizing at §414.90(h)(3) the following criterion for individual eligible professionals reporting individual PQRS quality measures via registry for the 2014 PQRS incentive: For the 12-month reporting period for the 2014 PQRS incentive, report at least 9 measures covering at least 3 of the NQS domains, OR, if less than 9 measures covering at least 3 NQS domains apply to the eligible professional, report 1—8 measures covering 1-3 NQS domains for which there is Medicare patient data, AND report each measure for at least 50 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate will not be counted. For an eligible professional who reports fewer than 9 measures covering less than 3 NQS domains, the eligible professional would be subject to the MAV process, which would allow us to determine whether an eligible professional should have reported on additional measures and/or measures covering additional NQS domains.

c. Changes to the Criterion for Satisfactory Reporting of Measures Groups via Claims for Individual
 Eligible Professionals for the 2014 PQRS Incentive

In the CY 2013 PFS final rule with comment period, we finalized the following criteria for satisfactory reporting for individual eligible professionals to report measures groups via claims: Report at least 1 measures group AND report each measures group for at least 20 Medicare Part B FFS patients. Measures groups containing a measure with a 0 percent performance rate will not be counted (77 FR 69192). Since finalizing this criterion, we published and analyzed the 2011 PQRS and eRx Experience Report, which provides a summary of PQRS reporting trends from 2007 through 2011, to determine where we may work to further streamline the reporting options available under the PQRS. The PQRS and eRx Experience Report stated that the number of eligible professionals who participated via claims-based measures groups reporting mechanism grew more than three-fold between 2008 and 2011. However, according to Appendix 8 of the PQRS and eRx Experience Report titled "Eligible Professionals who Participated by Reporting Measures Groups through the Claims Reporting Mechanism for the Physician Quality Reporting System, by Specialty (2008 to 2011)," only 4,472 eligible professionals used this reporting option. Meanwhile, the Experience Report further shows that the option to report measures

groups via registry has grown at an even faster rate with 12,894 participants in 2011. Therefore, in an effort to streamline the reporting options available under the PQRS and to eliminate reporting options that are not widely used, we proposed to remove this satisfactory reporting criterion for the 2014 PQRS incentive (78 FR 43359). We solicited and received the following public comments on this proposal:

<u>Comment</u>: Some commenters supported our proposal to eliminate the option to report measures groups via claims for the 2014 PQRS incentive in an effort to streamline the reporting options available under the PQRS.

<u>Response</u>: We appreciate the commenters' feedback and are finalizing this proposal.

Comment: Several commenters opposed our proposal to eliminate the option to report measures groups via claims for the 2014 PQRS incentive. Commenters stressed the need to maintain the claims-based reporting option, as some commenters are weary that moving away from the claims-based reporting mechanism will eliminate a free way to report quality measures under the PQRS (as most registries charge a fee to report PQRS quality measures data on behalf of its eligible professionals to CMS). Other commenters stressed the need to maintain a wide range of reporting options.

Response: We understand the commenters' desire to have free options to report under the PQRS. However, we do not believe it is necessary to maintain this reporting option, because an eligible professional may still use the free option of claims-based reporting to report individual quality measures for the 2014 PQRS incentive. In addition, we note that, while many qualified registries charge a fee for use of the registry, not all registries may charge a fee to use the registry to report quality measures for the PQRS. As you can see, although we are eliminating the option to report measures groups via claims, there are still ways to participate in the PQRS that are free.

For the commenters' desire to keep a wide range of PQRS reporting options available to eligible professionals, as we stated in the proposed rule (78 FR 43359), we simply do not see the need to keep this option available since this is not a widely used reporting option. We note that, although we are eliminating this reporting option, there are several other ways to participate in the PQRS either as an individual eligible professional or as part of a group practice under the GPRO. In fact, as we describe

below, we are adding the option to earn a 2014 PQRS incentive based on an eligible professional's satisfactory participation in a qualified clinical data registry.

For the reasons stated above, we are finalizing our proposal to eliminate the following criteria for satisfactory reporting for individual eligible professionals to report measures groups via claims for the 2014 PQRS incentive: Report at least 1 measures group AND report each measures group for at least 20 Medicare Part B FFS patients. Measures groups containing a measure with a 0 percent performance rate will not be counted. Please note that, as a result of our final decision to remove this satisfactory reporting criterion, the only manner in which an eligible professional will be able to report PQRS measures groups are via registry.

5. Criteria for Satisfactory Reporting for the 2016 PQRS Payment Adjustment for Individual Eligible Professionals using the Claims and Registry Reporting Mechanisms

Section 1848(a)(8) of the Act provides that for covered professional services furnished by an eligible professional during 2015 or any subsequent year, if the eligible professional does not satisfactorily report data on quality measures for covered professional services for the quality reporting period for the year, the fee schedule amount for services furnished by such professional during the year shall be equal to the applicable percent of the fee schedule amount that would otherwise apply to such services. For 2016 and subsequent years, the applicable percent is 98.0 percent.

In the CY 2013 PFS final rule, we finalized seven different criteria for the satisfactory reporting by individual eligible professionals of data in PQRS quality measures for the 2016 PQRS payment adjustment (see 77 FR 69200-69204 and Table 91 at 77 FR 69194). In the proposed rule, we proposed (78 FR 43360) to eliminate two criteria, revise another, and include two additional criteria (based on two of the existing criteria).

Specifically, corresponding with our proposal (78 FR 43360) to eliminate a reporting criterion for the 2014 PQRS incentive to streamline the program and eliminate criteria for reporting options that are not widely used, we proposed to remove the following criterion we previously finalized for the CY 2016 payment adjustment for individual eligible professionals reporting measures groups through claims (77

FR 69200 and Table 91, 77 FR 69164): Report at least 1 measures group AND report each measures group for at least 20 Medicare Part B FFS patients (Measures groups containing a measure with a 0 percent performance rate will not be counted). We solicited and received the following public comments on this proposal:

<u>Comment</u>: Some commenters supported our proposal to eliminate the option to report measures groups via claims for the 2016 PQRS payment adjustment in an effort to streamline the reporting options available under the PQRS.

Response: We appreciate the commenters' feedback and, based on the commenters' support and the reasons stated above, are finalizing this proposal.

<u>Comment</u>: Several commenters opposed our proposal to eliminate the option to report measures groups via claims for the 2016 PQRS payment adjustment. Commenters stressed the need to maintain the claims-based reporting option, as some commenters are weary that moving away from the claims-based reporting mechanism will eliminate a free way to report quality measures under the PQRS (as most registries charge a fee to report PQRS quality measures data on behalf of its eligible professionals to CMS).

Response: Although we understand the commenters' desire to have free options to report under the PQRS, we do not believe it is necessary to maintain this reporting option, because, as is also the case for reporting for the 2014 PQRS incentive, an eligible professional may still use the free option of claims-based reporting to report individual quality measures for the 2016 PQRS payment adjustment. In addition, we note that, while many qualified registries charge a fee for use of the registry, not all registries may charge a fee to use the registry to report quality measures for the PQRS. Although we are finalizing our decition to eliminate the option to report measures groups via claims, there are still ways to participate in the PQRS that are free.

As for the commenters' desire to keep a wide range of PQRS reporting options available to eligible professionals, we simply do not see the need to keep this option available since this is not a widely used reporting option. We note that, although we are eliminating this reporting option, there are

several other ways to participate in the PQRS either as an individual eligible professional or as part of a group practice under the GPRO. In fact, as we describe below, we are adding the option to avoid the 2016 PQRS payment adjustment based on an eligible professional's satisfactory participation in a qualified clinical data registry.

In summary, we are modifying §414.90(j)(3) to reflect our final decision to eliminate the following criteria for satisfactory reporting for individual eligible professionals to report measures groups via claims for the 2016 PQRS payment adjustment: Report at least 1 measures group AND report each measures group for at least 20 Medicare Part B FFS patients. Measures groups containing a measure with a 0 percent performance rate will not be counted. Please note that, since we are removing this reporting criterion, the only manner under which an eligible professional would be able to report a PQRS measures group would be via registry.

We also proposed (78 FR 43360) to remove the following criterion we previously finalized for the 2016 PQRS payment adjustment for individual eligible professionals reporting individual measures through a qualified registry: Report at least 3 measures, AND report each measure for at least 80 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measures applies. Measures with a 0 percent performance rate will not be counted. We solicited and received the following public comments on this proposal:

Comment: While several commenters supported our proposal to increase the number of measures to be reported via registry, these commenters generally did not support eliminating this reporting criterion. Some commenters did not support eliminating this reporting criterion as eligible professionals have previously met the criteria for satisfactory reporting using this criterion and therefore do not want to modify they manner in which they report. Other commenters expressed concern that there are still eligible professionals who do not have 3 measures applicable to their practice. These commenters therefore suggested that this criterion be modified to require the reporting of only 1 measure covering 1 NQS domain for the 2016 PQRS payment adjustment, similar to the criterion that was finalized for the

2015 PQRS payment adjustment (77 FR 69201), as some commenters are concerned that there are still eligible professionals who do not have 3 measures applicable to their practice.

Response: We understand the commenters' concerns regarding eliminating this reporting criterion. Although we still desire to move towards the reporting of more measures, we understand that eligible professionals may need another year to adjust to the reporting of additional measures. We believe it is pertinent to allow time for eligible professionals to adjust to the reporting of additional measures for purposes of the 2016 PQRS payment adjustment as opposed to the 2014 PQRS incentive, because earning a 2014 PQRS incentive results in a positive payment adjustment whereas beingsubject to the 2016 PQRS payment adjustment results in a downward payment adjustment. Therefore, based on the concerns expressed by commenters, we are not finalizing our proposal to eliminate this reporting criterion for the 2016 PQRS payment adjustment. We note, however, that it is our intention to move towards the reporting of 9 measures covering at least 3 NQS domains for the 2017 PQRS payment adjustment.

Since we are maintaining this satisfactory reporting criterion under the PQRS, and given that, as noted above, we are finalizing our proposal to reduce the percentage threshold of reporting measures via registry for purposes of the 2014 PQRS incentive from 80 to 50 percent, we are finalizing the same change for this reporting criterion for the 2016 PQRS payment adjustment. That is, to coincide with the registry reporting criterion for the 2014 PQRS incentive, we are also lowering the percentage threshold for the reporting of measures at least 3 measures via registry for the 2016 PQRS payment adjustment from 80 to 50 percent. We do not believe this change negatively affects eligible professionals who intend to report using this reporting criterion as this modification reduces reporting burden on eligible professionals. In addition, we note that, since the percentage threshold for the 2014 PQRS incentive typically coincides with the percentage threshold for the 2016 PQRS payment adjustment, it was foreseeable that we would lower the percentage threshold of reporting measures via registry for the 2016 PQRS payment adjustment from 80 to 50 percent since we proposed to lower the percentage threshold for the 2014 PQRS incentive.

For the commenters' who expressed concern that there are still eligible professionals who do not have 3 measures applicable to their practice, we are further modifing this satisfactory reporting criterion t o allow EPs to report 1-2 applicable measures if 3 measures are not applicable to the eligible professional. As a result, and consistent with the other similar criteria we are finalizing in this final rule with comment for the 2014 PQRS incentive, we will apply a registry MAV process for the 2016 PQRS payment adjustment. For purposes of this reporting criterion, the registry MAV process will be triggered when an eligible professional reports on less than 3 measures covering 1 NQS domain. For example, if an eligible professional reports on 1—2 measures, the MAV process will be triggered to determine whether an eligible professional could have reported on at least 3 measures covering 1 NQS domain.

This registry MAV process that will determine whether an eligible professional could have reported on more measures will be similar to the "clinical relation" test used in the 2013 claims MAV process. To get a better sense of how the registry MAV process for the 2016 PQRS payment adjustment will be implemented by CMS, a description of the "clinical relation" test in the current 2013 claims MAV process is available at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Downloads/2013_PQRS_MeasureApplicabilityValidation_Docs_030413.zip. Please note that we will post a guidance document on the registry MAV process for the 2016 PQRS payment adjustment, which will include a list of the measure clusters that are used for the "clinical relation" test, prior to January 1, 2014 (the start of the 2014 reporting periods).

In summary, for the reasons we noted above and in response to comments, we are not eliminating the following reporting criterion: Report at least 3 measures, AND report each measure for at least 80 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measures applies. Measures with a 0 percent performance rate will not be counted. Instead, we are retaining this reporting criterion for the 2016 payment adjustment for individual eligible professionals reporting individual measures through a qualified registry but modifying this reporting criterion in the following manner: For the 12-month reporting period for the 2016 PQRS payment adjustment, report at least 3 measures covering at least 1 of the NQS domains, OR, if less than 3 measures apply to the eligible

professional, report 1—2 measures covering 1 NQS domain for which there is Medicare patient data, AND report each measure for at least 50 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted. For an eligible professional who reports fewer than 3 measures covering 1 NQS domain via the registry-based reporting mechanism, the eligible professional would be subject to the MAV process, which would allow us to determine whether an eligible professional should have reported on additional measures.

Finally, to maintain some consistency and to otherwise align with the criteria we proposed for the 2014 PQRS incentive for individual eligible professionals, we proposed two other criteria for satisfactory reporting by individual eligible professionals for the 2016 PQRS payment adjustment using the claims reporting mechanism (78 FR 43360). We proposed (78 FR 43360) the following criterion for reporting individual measures via claims by individual eligible professionals for the 2016 PQRS payment adjustment: For the 12-month reporting period for the 2014 PQRS incentive, report at least 9 measures, covering at least 3 of the National Quality Strategy domains, OR, if less than 9 measures covering at least 3 NQS domains apply to the eligible professional, report 1–8 measures, and report each measure for at least 50 percent of the Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted.. We solicited and received the following comment on this proposed criterion:

<u>Comment</u>: One commenter stressed the importance of aligning the reporting criteria for the 2014 PQRS incentive with the reporting criteria for the 2016 PQRS payment adjustment, so that eligible professionals would be able to use one reporting option for the 2014 PQRS incentive and the 2016 PQRS payment adjustment.

Response: We appreciate the commenters' support regarding our desire to align reporting options for the 2014 PQRS incentive and 2016 PQRS payment adjustment. Based on the reasons previously stated and the positive feedback to align reporting options for the 2014 PQRS incentive and 2016 PQRS payment adjustment, we are finalizing the following criterion for reporting individual measures via claims

by individual eligible professionals for the 2016 PQRS payment adjustment: Report at least 9 measures covering at least 3 NQS domains, OR, if less than 9 measures covering at least 3 NQS domains apply to the eligible professional, report 1—8 measures covering 1—3 NQS domains, AND report each measure for at least 50 percent of the Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted. For an eligible professional who reports fewer than 9 measures covering at least 3 NQS domains via the claims-based reporting mechanism, the eligible professional would be subject to the MAV process, which would allow us to determine whether an eligible professional should have reported quality data codes for additional measures and/or covering additional NQS domains.

With respect to an eligible professional who reports on less than 9 measures and/or covering less than 3 NQS domains, the eligible professional must report on ALL measures covering as many domains as are applicable to the eligible professional's practice. In other words, with respect to an eligible professional who does not have 9 measures covering 3 NQS domains to report, the EP must report 1-8 measures, as applicable, and hit the maximum number of domains. For example, if an eligible professional has only 7 measures covering at least 3 NQS domains applicable to the eligible professional's practice, the eligible professional must report on all 7 measures covering at least 3 NQS domains.

We also proposed (78 FR 43360) the following criterion for reporting individual measures via qualified registry by individual eligible professionals for the 2016 PQRS payment adjustment: For the 12-month reporting period for the 2016 PQRS payment adjustment, report at least 9 measures covering at least 3 of the NQS domains and report each measure for at least 50 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted. We solicited and received the following public comment on this proposed criterion:

<u>Comment</u>: One commenter stressed the importance of aligning the reporting criteria for the 2014 PQRS incentive with the reporting criteria for the 2016 PQRS payment adjustment, so that eligible professionals would be able to use one reporting option for the 2014 PQRS incentive and the 2016 PQRS payment adjustment.

Response: We appreciate the commenters' feedback and are aligning reporting options for the 2014 PQRS incentive and 2016 PQRS payment adjustment to report individual measures via registry by individual eligible professionals.

<u>Comment</u>: The majority of commenters supported our proposal to decrease the percentage of patients that must be reported via registry from 80 percent to 50 percent. The commenters supported our proposal specifically because it aligns with the option to report individual measures via the claims-based reporting mechanism.

Response: We appreciate the commenters' feedback and, based on the support received and for the reasons stated in the proposed rule (78 FR 43360), we are finalizing this proposal with regard to the percent threshold. Therefore, to meet the criteria for satisfactory reporting for the 2016 PQRS payment adjustment, an eligible professional reporting individual quality measures via registry will be required to report each measure for at least 50 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies.

<u>Comment</u>: One commenter stated that we should not align the PQRS reporting criteria for reporting mechanisms other than the EHR-based reporting mechanisms with the reporting criteria for the EHR Incentive Program, as the objectives for the two programs are different.

Response: We respectfully disagree. Although the standards and criteria for which the PQRS and EHR Incentive Program provide incentives and relieve eligible professionals from payment adjustments are different, the two programs are both dedicated to the promotion of EHR technology and the collection of quality data.

<u>Comment</u>: The majority of commenters opposed our proposal to increase the number of measures to be reported via registry from 3 measures covering 1 NQS domain to 9 measures covering 3

NOS domains. Several of these commenters generally opposed any proposal that would increase the number of measures to be reported via registry from 3 measures covering 1 NQS domain. Some of these commenters noted that they have been successful at meeting the criteria for satisfactory reporting in the PQRS via registry in the past, and increasing the number of measures to be reported via registry would make it more difficult for these eligible professionals to meet the criteria for satisfactory reporting for the 2016 PQRS payment adjustment. Other commenters urged CMS not to increase the criteria for satisfactory reporting until participation in PQRS increases, as the commenters feared that increasing the criteria for satisfactory reporting in PORS would discourage eligible professionals from participating in the PQRS. Still some of these commenters opposing this proposal noted that certain eligible professionals did not have 9 measures covering 3 NQS domains for which to report. These commenters suggested requiring the reporting of either 4 measures covering at least 1 NQS domain, 5 measures covering at least 2 NQS domains, or 6 measures covering at least 2 NQS domains. Many of these commenters suggested requiring the reporting of only 1 measure covering 1 NOS domain for the 2016 PQRS payment adjustment, similar to the criterion that was finalized for the 2015 PQRS payment adjustment (see Table 91 at 77 FR 69194), as some commenters are concerned that there are still eligible professionals who do not have 3 measures applicable to their practice.

Response: We understand the commenters' concerns. As stated above, we are not finalizing our proposal to eliminate the option to report 3 measures covering 1 NQS domain (and further modifying it to allow the reporting of 1-2 meaures if 3 are not applicable). This should address some of the concerns raised regarding the proposed satisfactory criterion described above regarding increasing and moving away from reporting 3 measures. That also affords varying levels of reporting criteria from which to choose – particularly as participation increased. Therefore, eligible professionals will, at least for the 2016 PQRS payment adjustment, have the option to use an alternative, less stringent reporting criterion to generally report 3 individual quality measures for the 2016 PQRS payment adjustment via registry in lieu of this criterion.

As for this criterion and commenters' concerns about not having at least 9 PQRS measures covering 3 NQS domains, we are finalizing a modification to our proposal to allow eligible professionals to report fewer measures so that eligible professionals who do not have at least 9 PQRS measures or measures covering at least 3 NQS domains applicable to their practice. Specifically, if fewer than 9 measures covering less than 3 NQS domains apply to the eligible professional, an eligible professional must report 1-8 measures covering 1-3 NQS domains for which there is Medicare patient data. This is consisten with what we are finalizing with regard to certain 2014 PQRS incentive criteria. Similarly, the MAV process will be triggered when an eligible professional reports on less than 9 measures. For example, if an eligible professional reports on 8 measures covering 2 NQS domains, the MAV process will be triggered to determine whether an eligible professional could have reported on an additional measure to report on at least 9 measures covering 2 or 3 NQS domains.

In summary, we are finalizing at §414.90(j)(3) the following criterion for reporting individual measures via qualified registry by individual eligible professionals for the 2016 PQRS payment adjustment: Report at least 9 measures covering at least 3 of the NQS domains, OR, if less than 9 measures covering at least 3 NQS domains apply to the eligible professional, report 1—8 measures covering 1-3 NQS domains for which there is Medicare patient data, AND report each measure for at least 50 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate will not be counted. For an eligible professional who reports fewer than 9 measures, the eligible professional will be subject to the MAV process, which will allow us to determine whether an eligible professional should have reported on additional measures and/or measures covering additional NQS domains.

Please note that if an individual eligible professional were to meet any of the criteria for satisfactory reporting for the 2014 PQRS incentive, the individual eligible professional would meet the requirements for satisfactory reporting for the 2016 PQRS payment adjustment (note, however, that the reverse would not necessarily be true since there are additional criteria for satisfactory reporting for the 2016 PQRS payment adjustment that would not apply to the 2014 PQRS incentive). As we continue to

implement the PQRS payment adjustment and fully implement the value-based payment modifier in 2017, it is our intent to ramp up the criteria for satisfactory reporting for the 2017 PQRS payment adjustment to be on par or more stringent than the criteria for satisfactory reporting for the 2014 PQRS incentive.

6. Satisfactory Participation in a Qualified Clinical Data Registry by Individual Eligible Professionals

Section 601(b) of the American Taxpayer Relief Act of 2012 (ATRA) (Pub. L. 112–240, enacted January 2, 2013) amends section 1848(m)(3) of the Act, by redesignating paragraph (D) as subparagraph (F) and adding new subparagraph (D), to provide for a new standard for individual eligible professionals to satisfy the PQRS beginning in 2014, based on satisfactory participation in a qualified clinical data registry. In the CY 2014 PFS proposed rule (78 FR 43360), we set forth our proposals for implementing this provision, including the proposed requirements for qualified clinical data registries and our proposals for individual eligible professionals to satisfactorily participate in a qualified clinical data registry for the 2014 PQRS incentive and 2016 PQRS payment adjustment. Below, we address the final requirements related to satisfactory participation in a qualified clinical data registry by individual eligible professionals.

a. Definition of a Qualified Clinical Data Registry

Under section 1848(m)(3)(D) of the Act, as amended and added by section 601(b)(1) of the ATRA, for 2014 and subsequent years, the Secretary shall treat an eligible professional as satisfactorily submitting data on quality measures if, in lieu of reporting measures under subsection (k)(2)(C), the eligible professional is satisfactorily participating, as determined by the Secretary, in a qualified clinical data registry for the year. Section 1848(m)(3)(E) of the Act, as added by section 601(b)(1) of the ATRA, authorizes the Secretary to define a qualified clinical data registry under the PQRS. Specifically, the Secretary is required to establish requirements for an entity to be considered a qualified clinical data registry (including that the entity provide the Secretary with such information, at such times, and in such manner, as the Secretary determines necessary to carry out the provision). In establishing such requirements, the Secretary must take certain factors into consideration.

Based on CMS' authority to define a qualified clinical data registry under section 1848(m)(3)(E) of the Act, as added by section 601(b) of the ATRA, and accounting for the considerations addressed in section 1848(m)(3)(E)(ii) of the Act and for the reasons stated in the CY 2014 PFS proposed rule (78 FR 43361), we proposed to modify §414.90(b) to add a proposed definition for a qualified clinical data registry. Specifically, we proposed to define a "qualified clinical data registry" for purposes of the PQRS as a CMS-approved entity (such as a registry, certification board, collaborative, etc.) that collects medical and/or clinical data for the purpose of patient and disease tracking to foster improvement in the quality of care furnished to patients.

First, we proposed that a qualified clinical data registry must be able to submit quality measures data or results to CMS for purposes of demonstrating that, for a reporting period, its eligible professionals have satisfactorily participated in PQRS. We proposed that a qualified clinical data registry must have in place mechanisms for the transparency of data elements and specifications, risk models, and measures. We solicited and received the following public comment on this proposed aspect of the definition we proposed for a qualified clinical data registry:

Comment: Some commenters opposed our proposed requirement that an entity who seeks to become a qualified clinical data registry must be able to submit quality measures data or results to CMS for purposes of demonstrating that, for a reporting period, its eligible professionals have satisfactorily participated in PQRS. The commenters were generally opposed to requiring qualified clinical data registries to report on measures on behalf of its participating eligible professionals. These commenters believed that CMS should not require that a qualified clinical data registry be able to report on quality measures data if a clinical data registry is able to perform other important functions, such as benchmarking.

Response: We appreciate the commenters' feedback but respectfully disagree. We believe possessing the ability to submit quality measures data to CMS is an essential, not optional, aspect of a qualified clinical data registry. We believe collecting quality measures data from a qualified clinical data registry is essential, particularly so that the data received could be compared against eligible professionals

participating in PQRS using other reporting options to determine application of an upward, downward, or neutral adjustment under the Value-based Payment Modifier.

Second, with regard to the consideration under section 1848(m)(3)(E)(ii)(II) of the Act, as added by section 601(b) of the ATRA that allows the submission of data from participants for multiple payers, we proposed that the data a qualified clinical data registry submitted to CMS for purposes of demonstrating satisfactory participation be quality measures data on multiple payers, not just Medicare patients. We solicited and received the following public comment on this proposed aspect of our proposed definition of a qualified clinical data registry:

<u>Comment</u>: Several commenters supported our proposal to allow the reporting of quality measures data on multiple payers, not just Medicare patients.

Response: We appreciate the commenters' positive feedback and agree. Therefore, we are finalizing our proposal to include in the definition of a qualified clinical data registry the requirement that the data a qualified clinical data registry submitted to CMS for purposes of demonstrating satisfactory participation be quality measures data on multiple payers, not just Medicare patients.

Comment: Some commenters were weary of collecting quality measures data on multiple payers.

One of the commenters expressed concern that this could compel eligible professionals to collect and submit to a qualified clinical data registry patient data on multiple payers with no plan for utilizing the non-Medicare data or informing other payers that quality measure data have been collected on their patients.

Response: We respectfully disagree with the commenters. Please understand that, although the PQRS is a pay-for-reporting program, the data collected under the PQRS is used to measure performance and the quality of care an eligible professional provides. In fact, as specified in this final rule, the data collected under the PQRS reported by qualified clinical data registries will be used to measure performance of certain eligible professionals under the Value-based Payment Modifier.

Third, with regard to the consideration under section 1848(m)(3)(E)(ii)(III) of the Act, as added by section 601(b) of the ATRA, that a qualified clinical data registry provide timely performance reports

to participants at the individual participant level, we proposed that a qualified clinical data registry must provide timely feedback at least quarterly on the measures for which the qualified clinical data registry would report on the individual eligible professional's behalf for purposes of the eligible professional meeting the criteria for satisfactory participation under PQRS. We solicited and received the following public comment on this proposal:

Comment: Some commenters supported our proposal to require a qualified clinical data registry to provide timely feedback at least quarterly on the measures for which the qualified clinical data registry would report on the individual eligible professional's behalf for purposes of the eligible professional meeting the criteria for satisfactory participation under PQRS. However, other commenters expressed concern with this proposal, as it is costly and resource-intensive to provide quarterly feedback to all eligible professionals participating in a qualified clinical data registry. Some commenters requested clarification on the meaning of providing timely feedback at least quarterly on the measures for which the qualified clinical data registry would report on the individual eligible professional's behalf for purposes of the eligible professional meeting the criteria for satisfactory participation under PQRS. These commenters asked whether certain registries that allow users to generate reports on an "on demand" basis rather than directly pushing out feedback reports to its participate eligible professionals would meet the requirement of providing timely feedback at least quarterly to its eligible professionals.

Response: We appreciate the commenters' support, as well as concerns regarding this proposal. We understand the cost and resources a qualified clinical data registry would undergo to provide quarterly feedback to its participating eligible professionals. However, regardless of the cost, we believe that the ability to provide timely and frequent feedback to participating eligible professionals is critically important to fostering quality care. Please note that we currently require traditional qualified registries to provide at least 2 feedback reports to its participating eligible professionals per year. Since we view a qualified clinical data registry as an entity that is more robust than a traditional qualified registry and goes further to drive the quality of care provided to patients than only reporting quality measures data for the PQRS, we believe that requirements for an entity to become a qualified clinical data registry should be

more stringent than the requirements for a registry to be qualified under the PQRS. Therefore, we believe that a qualified clinical data registry should provide its participating eligible professionals with more than 2 feedback reports each year in which the clinical data registry is qualified. While we will not require a qualified clinical data registry to provide quarterly feedback reports, we are still requiring that a qualified clinical data registry provide at least 4 feedback reports to each of its participating eligible professionals during the year in which the clinical data registry is qualified (that is, if a qualified clinical data registry is qualified to report quality measures data for reporting periods occurring in 2014, the qualified clinical data registry must provide each participating eligible professional with at least 4 feedback reports in 2014).

We understand that some entities do not directly send feedback reports to its participating eligible professionals. Rather, these entities have feedback reports that are readily available for viewing at any time via the web or other communication mechanism. As one commenter specified, certain registries allow users to generate reports on an "on demand" basis rather than directly pushing out feedback reports to its participating eligible professionals. We note that this would fulfill the requirement that an entity seeking to be a qualified clinical data registry provide each participating eligible professional with at least 4 feedback reports per year.

Fourth, to address section 1848(m)(3)(E)(ii)(IV) of the Act, as added by section 601(b) of the ATRA, regarding whether a qualified clinical data registry supports quality improvement initiatives for its participants, we proposed (78 FR 43362) to require that a qualified clinical data registry possess a method to benchmark the quality of care measures an eligible professional provides with that of other eligible professionals performing the same or similar functions. Benchmarking would require that a qualified clinical data registry provide metrics to compare the quality of care its participating eligible professional provides. For example, the National Committee for Quality Assurance (NCQA) provides national and regional benchmarks for certain measures. Adopting benchmarks such as those provided by NCQA could serve to satisfy this requirement.

In addition to the comments received on our proposed definition of a qualified clinical data registry, we received the following general comments on the implementation of this new qualified clinical data registry option:

<u>Comment</u>: Several commenters supported the addition of the option to meet the criteria for satisfactory participation in a qualified clinical data registry for the PQRS. However, some commenters opposed this new option. Commenters were concerned that participation in a qualified clinical data registry requires considerable resources, ranging from subscription fees to the expertise of clinical personnel to abstract and report data.

Response: We understand the commenters' concerns regarding the expense of participating in a qualified clinical data registry. However, we note that it is voluntary for eligible professionals participate in the PQRS using a qualified clinical data registry. Rather, it is one of several reporting mechanisms that may be used to report quality measures data under the PQRS.

<u>Comment</u>: One commenter generally opposed the implementation of the option to satisfactorily participate in a qualified clinical data registry for purposes of the PQRS. The commenter stressed that adding another reporting option would add to the complexity of the program.

Response: We understand the commenters' concerns regarding adding complexity to the PQRS. Indeed, we have worked to streamline the PQRS to eliminate complexity in the program. However, under section 1848(m)(3)(D) of the Act, we are required to provide for a new standard for individual eligible professionals to satisfy the PQRS beginning in 2014, based on satisfactory participation in a qualified clinical data registry. Furthermore, we disagree with the commenter that this new qualified clinical data registry reporting option will add complexity to the PQRS, as this new option provides more flexibility than all other PQRS reporting options. For example, as explained in further detail in the PQRS measures section below, if reporting via a qualified clinical data registry, an eligible professional is not required to report on measures within the PQRS measure set.

In summary, we are amending §414.90(b) to define a qualified clinical data registry as a CMS-approved entity that has self-nominated and successfully completed a qualification process that collects

medical and/or clinical data for the purpose of patient and disease tracking to foster improvement in the quality of care provided to patients. A qualified clinical data registry must perform the following functions:

- (1) Submit quality measures data or results to CMS for purposes of demonstrating that, for a reporting period, its eligible professionals have satisfactorily participated in PQRS. A qualified clinical data registry must have in place mechanisms for the transparency of data elements and specifications, risk models, and measures.
- (2) Submit to CMS, for purposes of demonstrating satisfactory participation, quality measures data on multiple payers, not just Medicare patients
- (3) Provide timely feedback, at least four times a year, on the measures at the individual participant level for which the qualified clinical data registry reports on the eligible professional's behalf for purposes of the individual eligible professional's satisfactory participation in the clinical quality data registry.
- (4) Possess benchmarking capacity that measures the quality of care an eligible professional provides with other eligible professionals performing the same or similar functions.

Please note that it is possible for an entity to serve as both a traditional, qualified registry or a data submission vendor and a qualified clinical data registry under the PQRS.

b. Requirements for a Qualified Clinical Data Registry

As we noted above, we are required, under section 1848(m)(3)(E)(i) of the Act, to establish requirements for an entity to be considered a qualified clinical data registry. Such requirements shall include a requirement that the entity provide the Secretary with such information, at such times, and in such manner, as the Secretary determines necessary to carry out this subsection. Section 1848(m)(3)(E)(iv) of the Act, as added by section 601(b) of the ATRA, requires CMS to consult with interested parties in carrying out this provision.

Under this authority to establish the requirements for an entity to be considered a qualified clinical data registry, we proposed (78 FR 43362) the following requirements that an entity must meet to serve as a qualified clinical data registry under the PQRS:

<u>Comment</u>: Some commenters generally supported the stringent requirements we proposed for an entity to become a qualified clinical data registry.

Response: We appreciate the commenters' support for our proposals.

We proposed (78 FR 43362) the following requirements to ensure that the entity seeking to become a qualified clinical data registry is well-established:

• Be in existence as of January 1 the year prior to the year for which the entity seeks to become a qualified clinical data registry (for example, January 1, 2013, to be eligible to participate for purposes of data collected in 2014). This proposed requirement is also required of a traditional qualified registry.

We solicited and received the following public comments on this proposed requirement:

Comment: While some commenters generally supported this proposal as it help ensures that entities seeking to become qualified clinical data registries are established entities with experience in driving quality improvement in healthcare, a few commenters opposed our proposed requirement that, to become a qualified clinical data registry an entity must be in existence as of January 1 the year prior to the year for which the entity seeks to become a qualified clinical data registry (for example, January 1, 2013, to be eligible to participate for purposes of data collected in 2014). The commenters noted that this may alienate new and developing entities that already perform the functions required of a qualified clinical data registry.

Response: We understand that finalizing this requirement may exclude new entities that could perform the functions we require of a qualified clinical data registry. However, as we noted in the CY 2014 PFS proposed rule (78 FR 43362), we believe it is important for an entity to test out its business practices to ensure that the practices it adopts truly foster the improvement of quality care prior to seeking to become a qualified clinical data registry. We believe that entities that have been in existence for less than 1 year prior to the year for which the entity seeks to become a qualified clinical data registry have

not had an adequate opportunity to do so. We believe our reasons for proposing this requirement outweigh the commenters' concerns. Therefore, we are finalizing this proposal. For an entity to become qualified for a given year, the entity must be in existence as of January 1 the year prior to the year for which the entity seeks to become a qualified clinical data registry (for example, January 1, 2013, to be eligible to participate for purposes of data collected in 2014).

• Have at least 100 clinical data registry participants by January 1 the year prior to the year for which the entity seeks to submit clinical quality measures data (for example, January 1, 2013, to be eligible to participate under the program with regard to data collected in 2014). Please note that not all participants would be required to participate in PQRS (78 FR 43362).

We solicited and received the following public comments on this proposal:

<u>Comment</u>: Some commenters opposed this proposed requirement that an entity have at least 100 participants, because the commenters believe this requirement would effectively exclude smaller registries that perform important functions that provide for the advancement of quality care. Commenters felt that this proposed requirement unfairly favors larger entities that perform similar tasks.

Response: As we stated in the CY 2014 PFS proposed rule (78 FR 43362), we proposed this requirement to ensure that the entity seeking to become a qualified clinical data registry is sufficient in size and technical capability. Because we believe that a qualified clinical data registry should be more robust in technical capabilities than a traditional PQRS-qualified registry, we believe that a qualified clinical data registry should be sufficiently larger in size than a traditional PQRS-qualified registry, which is required to have at least 25 registry participants (77 FR 69179). Nonetheless, we understand the commenters' concerns. Although we do not believe we should drop the minimum threshold to 25, we believe it is reasonable to drop this proposed participation threshold to 50 participants. We believe that doubling the number of participants would ensure that the entities seeking to become qualified as a qualified clinical data registry would achieve our goal of attracting entities that are more robust in technical capabilities. In addition, we believe that the other requirements we are finalizing – such as the requirement that an entity seeking to become a qualified clinical data registry possess benchmarking

capabilities – will help to ensure that an entity seeking to become a qualified clinical data registry is well established. Therefore, for an entity to become qualified for a given year, we are adopting the requirement that the entity must have at least 50 clinical data registry participants by January 1 the year prior to the year for which the entity seeks to submit clinical quality measures data (for example, January 1, 2013, to be eligible to participate under the program with regard to data collected in 2014). Please note that not all participants would be required to participate in PQRS.

Comment: One commenter requested that we only require that an entity seeking to become a qualified clinical data registry have at least 100 clinical data registry participants by January 1 the year in which the entity seeks to submit clinical quality measures data (for example, January 1, 2014, to be eligible to participate under the program with regard to data collected in 2014) rather than the year prior to which the entity seeks to submit clinical quality measures data, because the commenter believes that this sufficiently ensures the legitimacy of an entity while providing entities with more time to gain participants.

Response: We appreciate the commenter's feedback. However, as we are requiring that a entity be in existence as of the year prior to which the entity seeks to participate in the PQRS as a qualified clinical data registry, we believe it is important that an entity have at least 50 participants the year prior to which the entity seeks to submit clinical quality measures data (for example, January 1, 2013 to be eligible to participate under the program with regard to data collected in 2014) to ensure that the entity is adequately established to participate in the PQRS as a qualified clinical data registry prior to the start of the reporting periods occurring in 2014.

• Not be owned or managed by an individual, locally-owned, single-specialty group (for example, single-specialty practices with only 1 practice location or solo practitioner practices would be precluded from becoming a qualified clinical data registry) (78 FR 43362). We solicited and received the following public comment on this proposed requirement:

<u>Comment</u>: Some commenters supported this proposal, as it encouraged shared care across specialties and groups. However, one commenter opposed this proposal, as the commenter does not

believe that a registry that covers patients within only a single group, even if multi-specialty or covering multiple states or regions, should meet the definition of a registry.

Response: We appreciate the commenter's support and, based on the commenters' support, are finalizing this requirement, as proposed.

In addition, for transparency purposes, we proposed (78 FR 43362) that a qualified clinical data registry must:

• Enter into and maintain with its participating professionals an appropriate Business Associate agreement that provides for the qualified clinical data registry's receipt of patient-specific data from the eligible professionals, as well as the qualified clinical data registry's public disclosure of quality measure results. We solicited and received the following public comment on this proposed requirement:

<u>Comment</u>: One commenter expressed concern with this proposed requirement, as the commenter believes that many registries will have to modify their business agreements to account for public disclosure of quality measure results.

Response: We understand the commenter's concerns on proposing to require that an entity's business agreement account for public disclosure of quality measure results. However, we believe that our desire for transparency in reporting outweighs the commenter's concerns. Therefore, we are finalizing this requirement, as proposed.

 Describe to CMS the cost for eligible professionals that the qualified clinical data registry charges to submit data to CMS (78 FR 43362). We solicited and received the following public comment on this proposed requirement:

Comment: One commenter supported this proposal.

Response: We appreciate the commenter's positive feedback and are finalizing this requirement, as proposed.

We also proposed (78 FR 43362) to require qualified clinical data registries to meet the following requirements pertaining to the transmission of quality measures data to CMS:

• To ensure that the qualified clinical data registry is compliant with applicable privacy and security laws and regulations, the entity must describe its plan to maintain Data Privacy and Security for data transmission, storage and reporting (78 FR 43362).

<u>Comment</u>: One commenter supported this proposal. Some commenters requested clarification as to how to successfully comply with certain security and privacy laws, as CMS has not provided specific guidance on how to maintain compliance with these laws.

Response: We understand the commenters' concerns regarding security and privacy laws related to the transmission of patient data. As addressing how to comply with applicable privacy and security laws and regulations is outside the scope of this final rule, we are simply finalizing a requirement that an entity seeking to be a qualified clinical data registry comply with these laws. Therefore, we are not providing additional guidance on this proposed requirement. However, we would expect that in developing a plan to maintain data privacy and security for data transmission, storage, and reporting, qualified clinical data registries would assess the laws and regulations governing such requirements and incorporate appropriate safeguards into their plans. We are finalizing these requirements, as proposed.

• Comply with a CMS-specified secure method for quality data submission (78 FR 43362). We solicited and received the following public comment on this proposed requirement:

Comment: One commenter supported this proposal.

Response: We appreciate the commenter's positive feedback and are finalizing this requirement, as proposed.

• Provide information on each measure to be reported by an eligible professional, including a summary of supporting evidence/rationale, title, numerator, denominator, exclusions/exceptions, data elements and value sets in addition to measure level reporting rates, patient-level demographic data and/or the data elements needed to calculate the reporting rates by TIN/NPI (78 FR 43362). We solicited and received the following public comment on this proposed requirement:

<u>Comment</u>: While one commenter supported the collection of aggregate quality measures data, the commenter opposed providing to CMS specific information that this proposed requirement suggests as it

is akin to requiring the reporting of patient-level data. The commenter requests clarification on this proposed requirement.

Response: Please note that this proposed requirement does not require reporting of patient-level data. Rather, this proposed requirement requires ta qualified clinical data registry to provide the measure specifications on each measure to be reported by an eligible professional. For more information on what level of specificity is needed, please refer to the 2013 PQRS Measures List available at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-
Instruments/PQRS/MeasuresCodes.html. For the reasons we explained, and since we received no direct opposition to this proposal, are finalizing this requirement, as proposed.

• Submit an acceptable "validation strategy" to CMS by March 31 of the reporting year the entity seeks qualification (for example, if an entity wishes to become qualified for participation with regard to data collected in 2014, this validation strategy would be required to be submitted to CMS by March 31, 2014). A validation strategy would detail how the qualified clinical data registry will determine whether eligible professionals succeed in reporting clinical quality measures. Acceptable validation strategies often include such provisions as the entity being able to conduct random sampling of their participant's data, but may also be based on other credible means of verifying the accuracy of data content and completeness of reporting or adherence to a required sampling method (78 FR 43362). For a template for data validation and integrity, please also see the requirements for certification of an EHR product by the Office of the National Coordinator for Health Information Technology (ONC) that are explained at http://www.healthit.gov/policy-researchers-implementers/2014-edition-final-test-method.

<u>Comment</u>: Some commenters supported this proposed requirement. Other commenters requested clarification on the definition of an acceptable "validation strategy."

Response: Please note that, to maintain flexibility, we did not identify a specific validation strategy. Rather, we outlined what such a validation strategy would need to demonstrate – namely, to determine whether eligible professionals succeed in reporting clinical quality measures. Should entities wishing to become qualified clinical data registries for 2014 require additional guidance and to vet their

strategies, CMS will provide guidance in subregulatory communication. Therefore, we are finalizing this proposal, as proposed.

• Perform the validation outlined in the strategy and send evidence of successful results to CMS by June 30 of the year following the reporting period (for example, June 30, 2015, for data collected in the reporting periods occurring in 2014) (78 FR 43363). We solicited and received the following public comment on this proposed requirement:

<u>Comment</u>: One commenter supported this proposed requirement.

Response: We appreciate the commenter's positive feedback and are finalizing this requirement, as proposed.

• Obtain and keep on file for at least 7 years signed documentation that each holder of an NPI whose data are submitted to the qualified clinical data registry has authorized the registry to submit quality measure results and numerator and denominator data and/or patient-specific data on beneficiaries to CMS for the purpose of PQRS participation. This documentation would be required to be obtained at the time the eligible professional signs up with the qualified clinical data registry to submit quality measures data to the qualified clinical data registry and would be required to meet any applicable laws, regulations, and contractual business associate agreements (78 FR 43363). We solicited and received the following public comment on this proposal:

<u>Comment</u>: One commenter supported this proposed requirement.

Response: We appreciate the commenter's positive feedback and are finalizing this requirement, as proposed.

• Upon request and for oversight purposes, provide CMS access to the qualified clinical data registry's database to review the beneficiary data on which the qualified clinical data registry-based submissions are based or provide to CMS a copy of the actual data (78 FR 43363). We solicited and received the following public comment on this proposal:

<u>Comment</u>: Several commenters opposed this proposed requirement, as the commenters fear that this would violate patient privacy laws. One of the commenters believes that both eligible professionals

and their patients would be opposed to this proposed requirement, as it provides CMS access to patient-level data.

Response: CMS shares the commenters' interest in ensuring the protection of individually identifiable health information. As a HIPAA Covered Entity, the Medicare program fully intends to limit its data demands to the minimum data necessary to achieve a statistically valid audit of the registry's submissions. We believe that such disclosures are well within the Privacy Rule's provisions governing "oversight" disclosures. For the reasons stated previously, we are finalizing this requirement, as proposed.

• Prior to CMS posting the list of qualified clinical data registries for a particular year, verify the information contained on the list (includes names, contact information, measures, cost, etc.) and agree to furnish/support all of the services listed on the list (78 FR 43363). We solicited and received the following public comment on this proposal:

<u>Comment</u>: One commenter supported this proposed requirement.

Response: We appreciate the commenter's positive feedback and are finalizing this requirement, as proposed.

 Make available to CMS samples of patient level data to audit the entity for purposes of validating the data submitted to CMS by the qualified clinical data registry, if determined to be necessary (78 FR 43363). We proposed this requirement to be able to conduct audits on clinical data registries for oversight purposes.

<u>Comment</u>: Several commenters opposed this proposed requirement, as the commenters fear that this would violate patient privacy laws. One commenter opposed this proposed requirement as it is duplicative of the proposed requirement to submit a validation strategy to CMS.

Response: CMS is tasked with overseeing the appropriate dispersal of funds from the Medicare trust fund, including the funds issued as PQRS payment incentives or adjustments made to fee schedule payments, as a result of PQRS reporting via qualified clinical data registries. This oversight is achieved through auditing the records CMS receives that serve as the basis for an amount paid out of the trust

fund. CMS intends to exercise its oversight authority in full conformance with the HIPAA Privacy Rule's provisions governing an oversight authority's access to the data to carry out their oversight functions.

With respect to the commenter who believes that this proposed requirement is unnecessary as it is duplicative of the proposed requirement to submit a validation strategy to CMS, we disagree. We are finalizing the requirement to submit a validation strategy to CMS so that CMS can determine whether the validation strategy used is sufficient to help ensure that accurate data is submitted to CMS. Although we proposed both requirements for oversight purposes, the requirement to make available to CMS samples of patient level data to audit the entity for purposes of validating the data submitted to CMS by the qualified clinical data registry, if determined to be necessary, would require more specific data to be made available to CMS. We note that, in all cases, we are requiring entities wishing to become qualified clinical data regsitries to submit its validation strategy to CMS, whereas we would only require that data be made available under this requirement only "if necessary." For the reasons stated previously, we are finalizing this requirement, as proposed.

• The entity must provide information on how the entity collects quality measurement data, if requested (78 FR 43363). We solicited and received the following public comment on this proposal:

Comment: One commenter supported this proposed requirement.

Response: We appreciate the commenter's positive feedback and are finalizing this requirement, as proposed.

• By March 31 of the year in which the entity seeks to participate in PQRS as a qualified clinical data registry, the entity must publically post (on the entity's website or other publication available to the public) a detailed description (rationale, numerator, denominator, exclusions/exceptions, data elements) of the quality measures it collects to ensure transparency of information to the public (78 FR 43363). We solicited and received the following public comment on this proposed requirement:

<u>Comment</u>: One commenter opposed the proposed March 31 deadline for an entity seeking to participate in the PQRS as a qualified clinical data registry to publically post a detailed description (rationale, numerator, denominator, exclusions/exceptions, data elements) of the quality measures it

collects to ensure transparency of information to the public. The commenter requested that this deadline be extended to June 1 of the year in which the entity seeks to participate in the PQRS as a qualified clinical data registry to allow time for these entities to prepare its measures for submission under this new reporting mechanism.

Response: We understand the commenter's concerns regarding the March 31 deadline. However, it is not technically feasible to accept this information later than the proposed March 31 deadline, as CMS must have time to be able to analyze the measure to determine how the measures data would be captured by CMS. Therefore, we are finalizing this requirement, as proposed.

- The entity must report, on behalf of its individual eligible professional participants, a minimum of 9 measures that cross 3 NQS domains (78 FR 43363). We solicited but received no public comment on this proposed requirement, as most comments were more specifically directed to our proposed criteria for satisfactory participation in a qualified clinical data registry for the 2014 PQRS incentive and 2016 PQRS payment adjustment, which we address below. However, since, as we specify below, we are not allowing a qualified clinical data registry to report less than 9 measures covering 3 NQS domains if less than 9 measures are applicable to its eligible professional participants, we are modifying this requirement in the following manner: the entity must report, on behalf of its individual eligible professional participants, a minimum of 9 measures that cross 3 NQS domains.
- The entity, on behalf of its individual eligible professional participants, must report on at least one outcomes-based measure (defined in this section below). (78 FR 43363)We solicited and received the following public comment on this proposed requirement (please note that most comments related to this proposed requirement were more specifically directed to our proposed criteria for satisfactory participation in a qualified clinical data registry for the 2014 PQRS incentive and 2016 PQRS payment adjustment):

<u>Comment</u>: One commenter supported this proposal as it furthers our focus on quality improvement. Other commenters requested clarification as to the definition of an outcome measure and

requested that certain measures be considered outcome measures for purposes of reporting these measures for the PQRS via a qualified clinical data registry.

Response: We appreciate the commenter's feedback and are finalizing this requirement, as proposed. Please note that we further clarify the definition of an outcome measure in the section below that describes the final parameters surrounding the measures for which a qualified clinical data registry may report for purposes of the PQRS.

• The entity, on behalf of its individual eligible professional participants, must report on a set of measures from one or more of the following categories: CG-CAHPS; NQF endorsed measures (information of which is available at http://www.qualityforum.org/Home.aspx); current PQRS measures; measures used by boards or specialty societies; and measures used in regional quality collaboratives (78 FR 43363). We solicited and received the following public comment on this proposed requirement:

<u>Comment</u>: One commenter supported this proposal as it furthers our focus on quality improvement.

Response: We appreciate the commenter's feedback and are finalizing this requirement, as proposed.

• The entity must demonstrate that it has a plan to publicly report its quality data through a mechanism where the public and registry participants can view data about individual eligible professionals, as well as view regional and national benchmarks. As an alternative, we considered requiring that the entity must benchmark within its own registry for purposes of determining relative quality performance where appropriate (78 FR 43363).

We solicited and received the following public comments on this proposal:

<u>Comment</u>: Several commenters opposed this proposed requirement, claiming that publicly reporting measures would be very costly to an entity. The commenters also stated that, if the entity did not already have an existing plan to publicly report measures, it would take entities a significant amount of time (over a year) to establish a plan to publicly report its measures.

Response: We understand the commenters' concerns regarding the cost, time, and other expenses associated with publicly reporting quality measures data. Please note that CMS only proposed that an entity demonstrate that a plan be developed, but did not explicitly propose that an entity wishing to become a qualified clinical data registry publicly report measures in 2014. Rather, as a first step, CMS was merely proposing that the entity have a plan in place to eventually publicly report their quality measures data. Regardless, due to the commenters' concerns, we are not finalizing this proposal at this time. We note, however, that CMS encourages these qualified clinical data registries to move towards the public reporting of quality measures data. We plan to establish such a requirement in the future and willrevisit this proposed requirement as part of CY 2015 rulemaking.

• The entity must demonstrate that it has a plan to risk adjust the quality measures data for which it collects and intends to transmit to CMS, where appropriate. Risk adjustment has been described as a corrective tool used to level the playing field regarding the reporting of patient outcomes, adjusting for the differences in risk among specific patients (http://www.sts.org/patient-information/what-risk-adjustment). Risk adjustment also makes it possible to compare performance fairly. For example, if an 86 year old female with diabetes undergoes bypass surgery, there is less chance for a good outcome when compared with a relatively healthier 40 year old male undergoing the same procedure. To take factors into account which influence outcomes, for example, advanced age, emergency operation, previous heart surgery, a risk adjustment model is used to report surgery results (78 FR 43363).

Comment: Several commenters supported this proposal as the commenters believe that risk adjustment is a critical component to ensure that the quality measures data submitted to CMS provides an accurate picture of the quality of care the eligible professional provides to its patients. Several other commenters, however, opposed the proposed requirement that the entity be required to demonstrate that it has a plan to risk adjust. While the commenters recognize that risk adjustment is a critical component of quality measurement, the commenters do not believe it should be a requirement for qualified clinical data registries currently since it is a resource intensive task and one for which there is no single proven model to ensure accuracy.

Response: We understand the costs associated with risk adjustment. However, we note that several comments responding to the Request for Information titled "Medicare Program; Request for Information on the Use of Clinical Quality Measures (CQMs) Reported Under the Physician Quality Reporting System (PQRS), the Electronic Health Record (EHR) Incentive Program, and Other Reporting Programs" (at 78 FR 9057) stressed the need to risk adjust quality measures data, and we agree. We believe this is especially important as the quality data submitted to CMS by qualified clinical data registries will be used to assess physician performance under the Value-based Payment Modifier. Therefore, for the reasons stated above, we are finalizing this proposal.

Please note that we are only requiring that the entity have a plan to risk adjust measures for which risk adjustment may be appropriate. If an entity has a plan to risk adjust its measures, we strongly encourage that this plan be made available to the public (such as having it posted on the entity's website). Please note that there are certain measures, such as process measures that only indicate the processes taken when performing a service, for which risk adjustment may not be appropriate.

Should CMS find, pursuant to an audit, that a qualified clinical data registry has submitted inaccurate data, CMS also proposed (78 FR 43363) to disqualify the qualified clinical data registry, meaning the entity would not be allowed to submit quality measures data on behalf of its eligible professionals for purposes of meeting the criteria for satisfactory participation for the following year. Should an entity be disqualified, we proposed that the entity must again become a qualified clinical data registry before it may submit quality measures data on behalf of its eligible professionals for purposes of the individual eligible professional participants meeting the criteria for satisfactory participation under the PQRS. Additionally, we proposed that the inaccurate data collected would be discounted for purposes of an individual eligible professional meeting the criteria for satisfactory participation in a qualified clinical data registry. We sought and received the following public comments on these proposals.

<u>Comment</u>: Some commenters opposed our proposal not to allow a qualified clinical data registry to re-submit quality measures data on behalf of its eligible professionals if CMS discovers the qualified

clinical data registry has submitted inaccurate data. The commenters believe that this proposal unnecessarily and negatively affects eligible professionals' success in the PQRS.

Response: We understand the commenters' concerns. However, it is not feasible to accept data later than the last Friday of the February immediately following the end of the respective reporting period (that is, February 27, 2015 for reporting periods occurring in 2014) and still be able to analyze the data in time to assess whether an eligible professional should be assessed a payment adjustment. Therefore, we are finalizing our proposal not to allow a qualified clinical data registry to re-submit quality measures data on behalf of its eligible professionals if CMS discovers the qualified clinical data registry has submitted inaccurate data, as proposed. We note that this limitation is consistent with other rules for reporting quality measures data via a qualified registry, a direct EHR product, or the EHR data submission vendor.

In summary, we are finalizing our proposals related to disqualification of a qualified clinical data registry, as proposed.

As we noted, section 1848(m)(3)(E)(i) of the Act, as added by section 601(b) of the ATRA, requires us to establish requirements for an entity to be considered a qualified clinical data registry, including that the entity provide us with such information, at such times, and in such manner, as we determine necessary to carry out the provision. Given the broad discretion afforded under the statute, we proposed that qualified clinical data registries provide CMS with the quality measures data it collects from its eligible professional participants. We believe it is important that a qualified clinical data registry provide such data for a number of reasons. As we discuss in greater detail below, we believe such information is necessary for purposes of determining whether individual eligible professionals have satisfactorily participated in a clinical qualified data registry under the PQRS. In addition, we proposed (78 FR 43485) to use the quality measures data reported under the PQRS to assess eligible professionals with regard to applying the value-based payment modifier in an upward, downward, and neutral adjustment to an eligible professional's Medicare Part B PFS charges. Therefore, we proposed to require that qualified clinical data registries submit quality measures data to CMS (78 FR 63363-43364).

Specifically, to further ensure that the quality measures data elements are reported to CMS in a

standardized manner, we proposed to require that qualified clinical data registries be able to collect all needed data elements and transmit the data on quality measures to CMS, upon request, in one of two formats, either via a CMS-approved XML format or via the Quality Reporting Document Architecture (QRDA) category III format. The CMS-approved XML format is consistent with how traditional qualified registries under the PQRS transmit data on quality measures to CMS. Although our preference would be to receive data on quality measures via the QRDA category III format only, since the QRDA category III format is one of the formats we require for an EP's EHR or an EHR data submission vendor to submit quality measures data (see 77 FR 69183), we noted that we understood that the quality measures data collected by qualified clinical data registries vary and that these qualified clinical data registries may not be equipped to submit quality measures data to CMS using the QRDA category III format. We stated that in future years, it was our intention to require all qualified clinical data registries to provide quality measures data via the QRDA category III format.

We solicited and received the following public comments on our proposal to accept quality measures data from a qualified clinical data registry in one of two formats, either via a CMS-approved XML format or via the QRDA category III format:

<u>Comment</u>: Several commenters supported our proposal to accept quality measures data in a CMS-approved XML format. Some commenters suggested clarification as to whether an qualified clinical data registry would have to be able to separate the reporting of Medicare vs. non-Medicare patients when submitting quality measures data to CMS.

Response: We appreciate the commenters' support, and based on the comments received and for the reasons stated above, are finalizing our proposal to accept quality measures data from a qualified clinical data registry in a CMS-approved XML format. Please note that CMS will not require the qualified clinical data registry submitting quality measures data on an eligible professional's behalf to separate the reporting of measures on the eligible professional's Medicare vs. non-Medicare patients.

<u>Comment</u>: Several commenters supported our proposal to accept quality measures data via the QRDA category III format, as this aligns with the format accepted under the EHR Incentive Program.

Response: We appreciate the commenters' feedback. However, after exploring the technological capabilities of our analysis systems, we have discovered that it is not technically feasible to accept quality measures data via a QRDA III format other than the electronically specified clinical quality measures (eCQMs) that may be reported to meet the CQM component of meaningful use under the EHR Incentive Program in 2014. In the future, we hope to further develop our analysis systems so that we are capable of accepting quality measures data via the QRDA category III format for additional measures. Therefore, for the reasons stated previously and based on the comments received, we are finalizing our proposal to accept quality measures data via the ORDA category III format exclusively for the 64 eCOMs that may be reported to meet the CQM component of meaningful use under the EHR Incentive Program in 2014 that are also reportable under the PQRS in 2014. We are finalizing the option to submit quality measures data via the QRDA category III format exclusively for the 64 eCQMs that may be reported to meet the CQM component of meaningful use under the EHR Incentive Program in 2014 because, unlike potential non-PORS measures that may be reported by eligible professionals in a qualified clinical data registry, we are already able to analyze the measures specifications for these measures. Since we do not currently have the measures specifications for the non-PQRS measures that will be submitted via a qualified clinical data registry, it is not feasible to test these measures to determine whether we are able to accept these measures data in a QRDA category III format.

To ensure that the data provided by the qualified clinical data registry is correct, we proposed to require that qualified clinical data registries provide CMS a signed, written attestation statement via e-mail which states that the quality measure results and any and all data including numerator and denominator data provided to CMS are accurate and complete (78 FR 43364). We solicited and received the following public comment on this proposal:

<u>Comment</u>: One commenter supported this proposed requirement.

<u>Response</u>: We appreciate the commenter's feedback and, based on the comments received and for the reasons stated above, are therefore finalizing this requirement, as proposed.

We proposed (78 FR 43364) that, regardless of whether the eligible professional uses the XML or QRDA III format to report quality measures data to CMS, the qualified clinical data registry would be required to submit this data no later than the last Friday occurring 2 months after the end of the respective reporting period (that is, February 27, 2015 for reporting periods occurring in 2014). We also proposed that, if a qualified clinical data registry is submitting quality measures data on behalf of individual eligible professionals that are part of the same group practice (but not participating in the PQRS GPRO), the qualified clinical data registry would have the option to report the quality measures data to CMS in a batch containing data for each of the individual eligible professionals within the group practice, rather than submitting individual files for each eligible professional (78 FR 43364). We solicited and received the following public comment on this proposal:

Comment: Some commenters requested that qualified clinical data registries be given more time to submit quality measures data to CMS, particularly since the qualified clinical data registry reporting mechanism is new. Some of these commenters requested that we extend the deadline to March 31 following the end of the respective reporting period (that is, March 31, 2015 for reporting periods occurring in 2014), at least for the first year in which a qualified clinical data registry must submit quality measures data to CMS.

Response: We appreciate the commenters' concerns. However, it is not technically feasible to accept quality measures data from qualified clinical data registries any later than the last Friday occurring 2 months after the end of the respective reporting period (that is, February 27, 2015 for reporting periods occurring in 2014). The additional time is needed to complete a thorough analysis of the submitted data prior to the application of the 2016 PQRS payment adjustment. Therefore, we are finalizing our proposal that a qualified clinical data registry would be required to submit this data no later than the last Friday occurring 2 months after the end of the respective reporting period (that is, February 27, 2015 for reporting periods occurring in 2014), as proposed.

In conjunction with our proposal to require that qualified clinical data registries be able to provide data on quality measures in a CMS-approved XML format, we proposed to require that qualified clinical

data registries report back to participants on the completeness, integrity, and accuracy of its participants' data (78 FR 43364). We believe that it would be beneficial to the participants to receive feedback on the data transmission process so that the participants are aware of any inaccuracies transmitted to CMS. We solicited and but received no public comment on this proposal. Therefore, we are finalizing this requirement, as proposed.

Alternatively, for the information CMS would require a qualified clinical data registry to furnish to CMS to determine that the eligible professionals have met the criteria for satisfactory participation for the 2014 PQRS incentive and 2016 PQRS payment adjustment, in lieu of accepting quality measures data for reporting periods occurring in 2014 only, we considered proposing (78 FR 43364) that a qualified clinical data registry provide CMS with a list of the eligible professionals (containing the respective eligible professionals' TIN/NPI information) who participated in and reported quality data to the qualified clinical data registry to determine which individual eligible professionals met the criteria for satisfactory participation for the 2014 PQRS incentive and 2016 PQRS payment adjustment. We considered this alternative because we do not have experience collecting data from qualified clinical data registries, we are unfamiliar with the type of quality data qualified clinical data registries collect, and we are still building out our data infrastructure. We solicited and received the following public comment on this alternative:

Comment: Several commenters preferred requiring a qualified clinical data registry provide CMS with a list of the eligible professionals (containing the respective eligible professionals' TIN/NPI information) who participated in and reported quality data to the qualified clinical data registry to determine which individual eligible professionals met the criteria for satisfactory participation for the 2014 PQRS incentive and 2016 PQRS payment adjustment in lieu of submitting actual quality measures data. Some of the commenters were concerned that a qualified clinical data registry seeking to participate in the PQRS would not be able to submit actual quality measures data to CMS in 2014, as the entities would not have enough time to adjust its systems to submit quality measures data in this initial year.

Response: We appreciate the commenters' feedback and understand the tight timeline that must be adhered to for a qualified clinical data registry to submit quality measures data to CMS for the 12-month reporting period occurring in 2014 for the 2014 PQRS incentive and 2016 PQRS payment adjustment. However, as for the reasons we noted above, we believe it is important to collect such data under the PQRS. Additionally, we note that for the Value-based Payment Modifier, which is based off of data submitted via the PQRS, to be able to accurately compare performance in the PQRS across eligible professionals, it is necessary to receive actual quality measures data from qualified clinical data registries. Therefore, we are not adopting this alternative.

Please note that we will post additional guidance and information on the requirements to become a qualified clinical data registry, as well as information on how a qualified clinical data registry will submit quality measures data for reporting periods occurring in 2014 on the PQRS website at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/index.html.

c. Process for Being Designated as a Qualified Clinical Data Registry

Secretary to establish a process to determine whether or not an entity meets the requirements established under section 1848(m)(3)(E)(i) of the Act. Such process may involve one or both of the following: (I) A determination by the Secretary; (II) A designation by the Secretary of one or more independent organizations to make such determination. This section sets forth our proposals for our process to determine whether or not an entity should be designated as a qualified clinical data registry.

Consistent with what we require of traditional qualified registries under the PQRS, we proposed that an entity must submit a self-nomination statement that indicates its intent to participate in PQRS as a qualified clinical data registry (78 FR 43364). We believe this self-nomination statement is necessary for CMS to anticipate how many clinical data registries would participate for a certain year, as well as provide information to eligible professionals about potential participating clinical data registries. We proposed that the self-nomination statement contain the following information:

• The name of the entity seeking to become a qualified clinical data registry.

- The entity's contact information, including phone number, email, and mailing address.
- A point of contact, including the contact's email address and phone number, to notify the entity of the status of its request to be considered a qualified clinical data registry.
- The measure title, description, and specifications for each measure the qualified clinical data registry would require its eligible professionals to report for purposes of participating in PQRS. In addition, the qualified clinical data registry must describe the rationale and evidence basis to support each measure it would require its eligible professionals to report.
 - The reporting period start date the entity will cover as a clinical data registry.

Since we believe that accepting these statements via email would be the most efficient method for collecting and processing self-nomination statements, we proposed to accept self-nomination statements via email only (78 FR 43364). However, in the event that it is not technically feasible to collect this self-nomination statement via email, we proposed that entities seeking to become qualified clinical data registries submit its self-nomination statement via a mailed letter to CMS. The self-nomination statement would be mailed to the following address: Centers for Medicare & Medicaid Services, Center for Clinical Standards and Quality, Quality Measurement and Health Assessment Group, 7500 Security Boulevard, Mail Stop S3-02-01, Baltimore, MD 21244-1850.

To ensure that CMS is able to process these self-nomination statements as early as possible, we proposed (78 FR 43364) that these self-nomination statements must be received by CMS by 5:00 p.m. Eastern Standard Time (e.s.t.) on January 31 of the year in which the clinical data registry seeks to be qualified (that is, January 31, 2014 for purposes of becoming a qualified clinical data registry for the reporting periods for the 2014 PQRS incentive and 2016 PQRS payment adjustment). We indicated that we anticipated posting a list of the entities that are designated by CMS as qualified clinical data registries in fall of the same year (78 FR 43365).

Since participation in a qualified clinical data registry is a new option for individual eligible professionals, we stated that we anticipated making changes to the requirements for becoming a qualified clinical data registry in future rulemaking as we gain more experience with this option. Since we believe

it is important that the entity keep up with these changes, at this time, we proposed that entities seeking to serve as qualified clinical data registries must self-nominate for each year that the entity seeks to participate (78 FR 43365). In the future, we noted we anticipated moving towards a multi-year self-nomination process as the requirements for qualified clinical data registries become firmly established; however, at this time, we proposed self-nomination for any year in which a qualified clinical data registry intends to participate under the PQRS.

We solicited and received the following public comment on these proposals:

Comment: Some commenters opposed our proposed deadline to receive self-nomination statements by January 31 of the year in which the clinical data registry seeks to be qualified. These commenters believed that this proposed deadline did not provide entities with enough time to decide whether they should seek to become a qualified clinical data registry, particularly since the final requirements for an entity to become a qualified clinical data registry would not be made available until the CY 2014 PFS final rule with comment period is displayed (approximately November 2013).

Response: We understand the commenters' concerns. However, as it is the first year in which this reporting mechanism will be implemented, it is not feasible to accept self-nomination statements later than Jaunary 31 of the year in which an entity seeks to become a qualified clinical data registry. CMS needs sufficient time to allow system updates to accommodate entities seeking to be qualified clinical data registries as well as work with entities who are seeking to become qualified clinical data registries.

Therefore, we are finalizing our proposed deadline to receive self-nomination statements from entities wishing to become qualified clinical data registry by 5:00 p.m. (e.s.t.) on January 31 of the year in which the clinical data registry seeks to be qualified (that is, January 31, 2014 for purposes of becoming a qualified clinical data registry for the reporting periods for the 2014 PQRS incentive and 2016 PQRS payment adjustment), as proposed.

<u>Comment</u>: Some commenters generally supported the proposed self-nomination process for entities wishing to become qualified as a qualified clinical data registry.

Response: We appreciate the commenters' response and, for the reasons stated above and based on the comments received, are finalizing this proposed process for being designated as a qualified clinical data registry, as proposed.

d. Reporting Period for the Satisfactory Participation by Individual Eligible Professionals in a Qualified
 Clinical Data Registry for the 2014 PQRS Incentive

Section 1848(m)(3)(D) of the Act, as redesignated and added by section 601(b) of the ATRA, authorizes the Secretary to treat an individual eligible professional as satisfactorily submitting data on quality measures under section 1848(m)(A) of the Act if the eligible professional is satisfactorily participating in a qualified clinical data registry for the year. Given that satisfactory participation is with regard to the year, and to provide consistency with the reporting period applicable to individual eligible professionals who report quality measures data under section 1848(m)(3)(A), we proposed to modify §414.90(c)(5) to specify a 12-month, calendar year (CY) reporting period from January 1, 2014 through December 31, 2014 for individual eligible professionals to satisfactorily participate in a qualified clinical data registry for purposes of the 2014 PQRS incentive (78 FR 43365). We invited and received the following public comment on the proposed 12-month, CY 2014 reporting period for the satisfactory participation of individual eligible professionals in a qualified clinical data registry for the 2014 PQRS incentive:

<u>Comment</u>: Some commenters provided general suggestions to align reporting periods for various CMS quality reporting programs wherever possible.

Response: We agree with the commenters. In fact, the proposed 12-month, CY 2014 reporting period for the satisfactory participation of individual eligible professionals in a qualified clinical data registry for the 2014 PQRS incentive aligns with the 12-month CY 2014 reporting period for meeting the criteria for satisfactory reporting for the 2014 PQRS incentive. Therefore, we are adding paragraph §414.90(i)(1) to specify a 12-month, CY 2014 reporting period for the satisfactory participation of individual eligible professionals in a qualified clinical data registry for the 2014 PQRS incentive, as proposed.

e. Criteria for Satisfactory Participation for Individual Eligible Professionals In a Qualified Clinical Data Registry for the 2014 PQRS Incentive

For 2014, in accordance with §414.90(c)(3), eligible professionals that satisfactorily report data on PQRS quality measures are eligible to receive an incentive equal to 0.5 percent of the total estimated Medicare Part B allowed charges for all covered professional services furnished by the eligible professional or group practice during the applicable reporting period. Section 1848(m)(3)(D) of the Act, as redesignated and added by section 601(b) of the ATRA, authorizes the Secretary to treat an individual eligible professional as satisfactorily submitting data on quality measures under section 1848(m)(A) of the Act if, in lieu of reporting measures under section 1848(k)(2)(C) of the Act, the eligible professional is satisfactorily participating in a qualified clinical data registry for the year. "Satisfactory participation" is a new standard under the PQRS and is a substitute for the underlying standard of "satisfactory reporting" data on covered professional services that eligible professionals must meet to earn a PQRS incentive or avoid the PORS payment adjustment. Therefore, we proposed to modify §414.90 to add paragraph (c)(5) to indicate that individual eligible professionals shall be treated as satisfactorily reporting data on quality measures if individual eligible professionals satisfactorily participate in a qualified clinical data registry for purposes of the PQRS incentive (78 FR 43365). We solicited but received no public comment on this proposal. Therefore, we are finalizing our proposal to modify §414.90 to add paragraph (c)(5) to indicate that individual eligible professionals shall be treated as satisfactorily reporting data on quality measures if individual eligible professionals satisfactorily participate in a qualified clinical data registry for purposes of the PQRS incentive, as proposed.

In addition, to establish a standard for satisfactory participation in a qualified clinical data registry, we proposed that, to meet the criteria for satisfactory participation for the 2014 PQRS incentive, an individual eligible professional would be required to: For the 12-month 2014 reporting period, report at least 9 measures available for reporting under the qualified clinical data registry covering at least 3 of the NQS domains, OR, if less than 9 measures apply to the eligible professional, report 1—8 measures, AND report each measure for at least 50 percent of the eligible professional's applicable patients. Of the

measures reported via a qualified clinical data registry, the eligible professional must report on at least 1 outcome measure (78 FR 43365). We solicited and received the following public comment for these proposals:

<u>Comment</u>: Several commenters opposed our proposal to require that, of the measures reported via a qualified clinical data registry, the eligible professional must report on at least 1 outcome measure. Some of these commenters noted that, there are many specialties for which outcomes measures may not yet be available, hindering these specialties from participating in the PQRS via a qualified clinical data registry.

Response: We understand that certain specialties may not have outcome measures for which they may report. However, we believe it is important to emphasize the reporting of outcomes measures, as we believe they provide better metrics in the quality of care an eligible professional provides than process measures do. To encourage the reporting of outcome measures, we are therefore finalizing our proposal to require that, of the measures reported via a qualified clinical data registry to meet the criteria for satisfactory participation in a qualified clinical data registry for the 2014 PQRS incentive, the eligible professional must report on at least 1 outcome measure.

Comment: Several commenters supported our proposal to require that an eligible professional report each measure for at least 50 percent of the eligible professional's applicable patients. The commenters supported our proposal specifically because it aligns with the option to report individual measures via the claims-based reporting mechanism. One commenter, however, opposed this proposal. Instead, the commenter suggested that CMS allow a qualified clinical data registry to submit its verifiable, statistically supported sampling methodology to CMS for review and require eligible professionals to report a sufficient number of cases as determined by the individual registry's sampling requirements.

Response: We appreciate the commenters' positive feedback. For the suggestion to allow a qualified clinical data registry to submit quality measures data based on an approved sampling methodology created by the clinical data registry, we do not believe this is sufficient for the PQRS at this

time. Particularly since the quality measures data received through the PQRS will be used to assess eligible professionals under the Value-based Payment Modifier, we believe it is important to receive data consistent with the data we are receiving via the claims and registry-based reporting mechanisms. Therefore, we are finalizing this proposal. For the 2014 PQRS incentive, an eligible professional reporting individual quality measures via a qualified clinical data registry will be required to report each measure for at least 50 percent of the eligible professional's applicable patients. Please note, however, that as the program evolves, we anticipate increasing the reporting threshold for the qualified clinical data registry reporting mechanism.

<u>Comment</u>: While several commenters generally supported our proposal to require the reporting of more than 3 measures, the commenters believed that requiring the reporting of at least 9 measures covering at least 3 of the NQS domains is too onerous. These commenters suggested requiring the reporting of either 4 measures covering at least 1 NQS domain, 5 measures covering at least 2 NQS domains, or 6 measures covering at least 2 NQS domains.

Response: We appreciate the commenters' support for our desire to require the reporting of more than 3 measures to meet the criteria for satisfactory participation in a qualified clinical data registry for the 2014 PQRS incentive. For purposes of the 2014 PQRS incentive, we believe that requiring the reporting of 9 measures is appropriate for satisfactory participation, as the proposal is consistent with the requirement for an eligible professional to report on at least 9 individual measures to meet the criteria for satisfactory reporting for the 2014 PQRS incentive. In fact, while we understand the commenters' concerns that an eligible professional reporting via the claims or traditional registry may not have 9 relevant measures for which to report, we do not believe the same argument can be made for an eligible professional reporting quality measures data via a qualified clinical data reporting. An eligible professional reporting via a qualified clinical data registry is not limited to reporting on measures within the PQRS measure set. Rather, an eligible professional using the qualified clinical data registry reporting mechanism may report on measures that are outside of the PQRS measure set. Based on the comments received and for the reasons stated previously, we are finalizing our proposal to require an individual

eligible professional using a qualified clinical data registry to report on at least 9 measures for the PQRS incentive.

<u>Comment</u>: Several commenters generally supported the reporting of measures across multiple NQS domains, as reporting on a variety of measures provides eligible professionals with a better picture of the full continuum of care provided.

Response: We agree with the commenters. Based on the comments received, we are finalizing our proposal to require an individual eligible professional using a qualified clinical data registry to report on at least 9 measures covering at least 3 of the NQS domains for the 2014 PQRS incentive.

<u>Comment</u>: Several commenters supported our proposal to allow an eligible professional to report less than 9 measures, should less than 9 measures be applicable to the eligible professional. Several of the commenters sought clarification on how CMS would determine whether additional measures could be reported by an eligible professional.

Response: We appreciate the commenters' feedback. Unfortunately, at this time, it is not feasible for us to finalize an option to report on less than 9 measures via a qualified clinical data registry for the 2014 PQRS incentive. In order to do so, we believe we would need to apply the MAV process. Although we are able to implement a MAV process for the claims and registry-based reporting mechanisms to determine whether an eligible professional could have reported on additional measures, we are unable to implement a similar process for the qualified clinical data registry-based reporting mechanism as the measures that may be reported via a qualified clinical data registry are not required to be measures found in the PQRS measure set. Therefore, it would be difficult for CMS to determine appropriate measure clusters for the MAV process. Until we can implement a MAV process where we are able to accurately identify the measure clusters, we do not believe it is appropriate to adopt such a change to the criterion. Therefore, eligible professionals must report on at least 9 measures covering at least 3 of the NQS domains.

<u>Comment</u>: Several commenters urged CMS to allow the reporting of measures groups under the qualified clinical data registry reporting mechanism for the 2014 PQRS incentive.

Response: We agree with the commenters. However, please note that we are not restricting this reporting criterion to individual measures. Rather, as we discuss in greater detail in the PQRS measures section below, a qualified clinical data registry is free to choose which measures its participants will report for purposes of the PQRS. Should a qualified clinical data registry require its eligible professionals to report on a cluster of measures similar to PQRS measures groups, the measures within the measures group would count as separate, individual measures.

Based on the comments received and for the reasons explained previously, as we specify in §414.90(i), we are finalizing the following criteria for an individual eligible professional to meet the criteria for satisfactory participation for the 2014 PQRS incentive: For the 12-month 2014 reporting period, report at least 9 measures available for reporting under the qualified clinical data registry covering at least 3 of the NQS domains AND report each measure for at least 50 percent of the eligible professional's applicable patients. Of the measures reported via a qualified clinical data registry, the eligible professional must report on at least 1 outcome measure.

We further proposed that a qualified clinical data registry may submit data on more than 9 quality measures on behalf of an eligible professional (78 FR 43365). However, we proposed that a qualified clinical data registry may not submit data on more than 20 measures on behalf of an eligible professional. We proposed to place a limit on the number of measures that a qualified clinical data registry may submit on behalf of an eligible professional at this time because we have no experience with qualified clinical data registries and the types of data on quality measures that they collect. We solicited and but received no public comment on this proposal.

Although we have the capacity to accept quality measures data from all measures finalized in the PQRS measure set specified in Table 52, in analyzing our capability to accept quality measures data, we discovered that it would not be feasible for CMS to accept quality measures data on more than 20 measures not specieid in Table 52 from a qualified clinical data registry at this time. CMS needs to have adequate time to analyze the measures provided to determine how the quality measures data will be calculated. We solicied but received no public comment on this proposal. Therefore, for the reasons

stated above, we are capping the number of non-PQRS measures CMS may receive from each qualified clinical data registry to 20 so as not to be inundated with measures whose specifications must be analyzed prior to the submission deadline for qualified clinical data registries to submit quality measures data to CMS. Therefore, we are limiting the number of quality measures a qualified clinical data registry may submit to no more than 20 measures not specified in Table 52 on behalf of an eligible professional. Qualified clinical data registries may submit quality measures data on any or all measures specified in Table 52 of this final rule with comment period. As the qualified clinical data registry reporting option develops, we hope to be able to accept data on more quality measures outside of the PQRS measure set in the future. Please note that this restriction also applies to measures being reported to meet the criteria for satisfactory participation in a qualified clinical data registry for the 2016 PQRS payment adjustment.

f. Reporting Period for the Satisfactory Participation for Individual Eligible Professionals in a Qualified Clinical Data Registry for the 2016 PQRS Payment Adjustment

Section 1848(m)(3)(D) of the Act, as redesignated and added by section 601(b) of the ATRA, authorizes the Secretary to treat an individual eligible professional as satisfactorily submitting data on quality measures under section 1848(m)(A) of the Act if the eligible professional is satisfactorily participating in a qualified clinical data registry for the year. Given that satisfactory participation is with regard to the year, and to provide consistency with how individual eligible professionals report quality measures data to a qualified clinical data registry, we proposed to modify §414.90(e)(2) to specify a 12-month, calendar year (CY) reporting period from January 1, 2014 through December 31, 2014, for individual eligible professionals to satisfactorily participate in a qualified clinical data registry for purposes of the 2016 PQRS payment adjustment (78 FR 43366). We invited and received the following public comments on the proposed 12-month, CY 2014 reporting period (that is, January 1, 2014 – December 31, 2014) for the satisfactory participation of individual eligible professionals in a qualified clinical data registry for the 2016 PQRS payment adjustment:

<u>Comment</u>: Several commenters opposed our proposal to base the 2016 PQRS payment adjustment year on a reporting period occurring 2 years prior to the payment adjustment year. The commenters believe that the reporting period should occur closer to the payment adjustment year.

Response: We understand the commenters' concerns on establishing a reporting period 2 years prior to the payment adjustment year. However, it is not operationally feasible to create a full calendar year reporting period for the 2016 PQRS payment adjustment any later than 2 years prior to the adjustment year and still avoid retroactive payments or the reprocessing of claims. Section 1848(a)(8) of the Act requires that a payment adjustment be applied to covered professional services furnished by an eligible professional in the particular payment adjustment year. Therefore, we believe it is necessary to reduce the PFS amount concurrently for PFS allowed charges for covered professional services furnished in 2016. If we do not reduce the PFS amount concurrently with claims submissions in 2016, we would need to potentially recoup or provide added payments after the determination is made about whether the payment adjustment applies, or alternatively, hold claims until such a determination is made. In addition, we note that if such retroactive adjustments were made it may require a reconciliation of beneficiary copayments. As a result, we need to determine whether eligible professionals have satisfactorily reported under the PORS based on a reporting period that occurs prior to 2016. For the reasons stated here and above, we are specifying under §414.90(k)a 12-month, CY 2014 reporting period (that is, January 1, 2014 - December 31, 2014) for the satisfactory participation of individual eligible professionals in a qualified clinical data registry for the 2016 PQRS payment adjustment. As we stated in the proposed rule (78 FR 43366), this final reporting period for the 2016 PORS payment adjustment is consistent with the 2016 PQRS payment adjustment reporting periods for all other reporting mechanisms.

g. Criteria for the Satisfactory Participation for Individual Eligible Professionals in a Qualified Clinical Data Registry for the 2016 PQRS Payment Adjustment

Section 1848(a)(8) of the Act provides that for covered professional services furnished by an eligible professional during 2015 or any subsequent year, if the eligible professional does not satisfactorily report data on quality measures for covered professional services for the quality reporting

period for the year, the fee schedule amount for services furnished by such professional during the year shall be equal to the applicable percent of the fee schedule amount that would otherwise apply to such services. For 2016 and subsequent years, the applicable percent is 98.0 percent.

Section 1848(m)(3)(D) of the Act, as redesignated and added by section 601(b) of the ATRA, authorizes the Secretary to treat an individual eligible professional as satisfactorily submitting data on quality measures under section 1848(m)(A) of the Act if, in lieu of reporting measures under section 1848(k)(2)(C) of the Act, the eligible professional is satisfactorily participating in a qualified clinical data registry for the year. "Satisfactory participation" is a new standard under the PQRS and is a substitute for the underlying standard of "satisfactory reporting" data on covered professional services that eligible professionals must meet to earn a PQRS incentive or avoid the PQRS payment adjustment. Therefore, we proposed to modify

§ 414.90 to add paragraph (e)(2) to indicate that individual eligible professionals shall be treated as satisfactorily reporting data on quality measures, if the individual eligible professional satisfactorily participates in a qualified clinical data registry (78 FR 43366). We solicited but received no public comment on this proposal. Therefore, we are modifying §414.90 to indicate that individual eligible professionals shall be treated as satisfactorily reporting data on quality measures, if the individual eligible professional satisfactorily participates in a qualified clinical data registry. However, as some of the paragraphs have changed since this proposal, we are not indicating this change in paragraph (e)(2). Rather, we are adding paragraph §414.90(k) to indicate that individual eligible professionals shall be treated as satisfactorily reporting data on quality measures, if the individual eligible professional satisfactorily participates in a qualified clinical data registry.

For purposes of the 2016 PQRS payment adjustment (which would be based on data reported during the 12-month period that falls in CY 2014), we proposed the exact same requirement we proposed above for satisfactory participation for the 2014 PQRS incentive (78 FR 43366). Specifically, we proposed the following criteria for an individual eligible professional to meet the criteria for satisfactory participation for the 2016 PQRS payment adjustment: For the 12-month reporting period for the 2016

PQRS payment adjustment, report at least 9 measures available for reporting under the qualified clinical data registry covering at least 3 of the NQS domains; AND report each measure for at least 50 percent of the eligible professional's applicable patients. Of the measures reported via a qualified clinical data registry, the eligible professional must report on at least 1 outcome measure (78 FR 43367, Table 25). We solicited and received the following public comments on the proposed criterion for the satisfactory participation by individual eligible professionals in a qualified clinical data registry for the 2016 PQRS payment adjustment:

<u>Comment</u>: Several commenters urged CMS to allow the reporting of measures groups under the qualified clinical data registry reporting mechanism for the 2016 PQRS payment adjustment.

Response: We agree with the commenters. However, please note that we are not restricting this reporting criterion to individual measures. Rather, as we discuss in greater detail in the PQRS measures section below, a qualified clinical data registry is free to choose which measures its participants will report for purposes of the PQRS. Should a qualified clinical data registry require its eligible professionals to report on a cluster of measures similar to PQRS measures groups, the measures within the measures group would count as separate, individual measures.

Comment: Several commenters supported our proposal to require that an eligible professional report each measure for at least 50 percent of the eligible professional's applicable patients. The commenters supported our proposal specifically because it aligns with the option to report individual measures via the claims-based reporting mechanism. One commenter, however, opposed this proposal. Instead, the commenter suggested that CMS allow a qualified clinical data registry to submit its verifiable, statistically supported sampling methodology to CMS for review and require eligible professionals to report a sufficient number of cases as determined by the individual registry's sampling requirements.

Response: We appreciate the commenters' positive feedback. For the suggestion to allow a qualified clinical data registry to submit quality measures data based on an approved sampling methodology created by the clinical data registry, we do not believe this is sufficient for the PQRS at this

time. Particularly since the quality measures data received through the PQRS will be used to assess eligible professionals under the Value-based Payment Modifier, we believe it is important to receive data consistent with the data we are receiving via the claims and registry-based reporting mechanisms.

Therefore, we are finalizing our proposal to use a 50 percent threshold. For the 2016 PQRS payment adjustment, an eligible professional reporting individual quality measures via a qualified clinical data registry will be required to report on at least 3 measures and report each measure for at least 50 percent of the eligible professional's applicable patients. Comment: While several commenters generally supported our proposal to require the reporting of more than 3 measures, the commenters believed that requiring the reporting of at least 9 measures covering at least 3 of the NQS domains is too onerous, especially for the PQRS payment adjustment. These commenters suggested requiring the reporting of either 4 measures covering at least 1 NQS domain, 5 measures covering at least 2 NQS domains, or 6 measures covering at least 2 NQS domains.

Response: We appreciate the commenters' support for our desire to require the reporting of more than 3 measures to meet the criteria for satisfactory participation in a qualified clinical data registry for the 2014 PQRS incentive. To be consistent with the criterion we are finalizing for the 2014 PQRS incentive, we are requiring that an eligible professional report on at least 9 measures covering at least 3 NQS domains.

However, we believe it is appropriate to finalize less stringent criteria for the 2016 PQRS payment adjustment, particularly since the qualified clinical data registry is a new reporting mechanism for 2014. We believe this is especially helpful for those eligible professionals who use current qualified registries that will seek to become qualified clinical data registries for 2014 that have traditionally reported 3 measures covering 1 domain to meet the criteria for satisfactory reporting in the PQRS.

Therefore, to be consistent with the the criterion we are finalizing for individual eligible professionals to reporting individual measures registry for the 2016 PQRS payment adjustment, an individual eligible professional using a qualified clinical data registry may report on at least 3 measures for at least 50 percent of the eligible professional's applicable patients to satisfy the criteria for satisfactory participation

in a qualified clinical data registry for the 2016 PQRS payment adjustment. Please note that it is our intention to fully move towards the reporting of 9 measures covering at least 3 domains to meet the criteria for satisfactory participation for the 2017 PQRS payment adjustment.

<u>Comment</u>: Several commenters opposed our proposal to require that, of the measures reported via a qualified clinical data registry, the eligible professional must report on at least 1 outcome measure. Some of these commenters noted that, there are many specialties for which outcomes measures may not yet be available, hindering these specialties from participating in the PQRS via a qualified clinical data registry.

Response: To be consistent with criterion we are finalizing for the 2014 PQRS incentive, if an eligible professional wants to meet the criteria for satisfactory participation for the 2014 PQRS incentive AND 2016 PQRS payment adjustment, we are requiring that an eligible professional who reports at least 9 measures covering at least 3 NQS domains report on at least 1 outcome measure.

However, for eligible professionals who only seek to meet the criteria for satisfactory participation for the 2016 PQRS payment adjustment (for example, not seek to earn a 2014 PQRS incentive), we understand that not all entities seeking to become qualified clinical data registries may have outcome measures available for its eligible professionals to report. For example, we understand that registries created for eligible professionals whose primary function is to perform imagining scans have found it difficult to develop outcome measures, as outcomes are usually measures not with those particular eligible professionals but by other eligible professionals for which a patient primarily sees.

Unlike the PQRS incentive, we believe that, for purposes of the 2016 PQRS payment adjustment only, it is appropriate for this initial year not to finalize the requirement to report an outcome measure.

Therefore, if reporting for the 2016 PQRS payment adjustment only and not seeking to earn a 2014 PQRS incentive, if an eligible professional is reporting 3 measures covering at least 1 NQS domain, we will not require an eligible professional to report on at least 1 outcome measure. Please note, however, that it is our intention to require the reporting of 1 outcome measure if reporting via a qualified clinical data registry for the 2017 PQRS payment adjustment. Therefore, we encourage these registries that do not

currently require the reporting of an outcome measure to find ways for which an outcome measure may be developed.

<u>Comment</u>: Several commenters generally supported the reporting of measures across multiple NQS domains, as reporting on a variety of measures provides eligible professionals with a better picture of full continuum of care provided.

Response: We agree with the commenters. To be consistent with the criterion we are finalizing for the 2014 PQRS incentive, we are requiring that an eligible professional report on measures covering at least 3 NQS domains.

However, since we are also finalizing an alternative criterion only requiring that an eligible professional using a qualified clinical data registry report on at least 3 measures for the 2016 PQRS payment adjustment, as well as to be consistent with the criterion we finalized for an individual eligible professional reporting individual quality measures via registry for the 2016 PQRS payment adjustment, for purposes of the 2016 PQRS payment adjustment only, we are finalizing a decision to require that an eligible professional using a qualified clinical data registry report on at least 3 measures covering only 1 NQS domain.

<u>Comment</u>: Several commenters supported our proposal to implement a MAV process, in the event an eligible professional reports 1—8 measures because less than 9 measures are applicable to the eligible professional. Several of the commenters sought clarification on how CMS would determine whether additional measures could be reported by an eligible professional.

Response: We appreciate the commenters' feedback and support for implementing a MAV process for eligible professionals reporting via a qualified clinical data registry. Unfortunately, although we are able to implement a MAV process for the claims and registry-based reporting mechanisms to determine whether an eligible professional could have reported on additional measures, we are unable to implement a similar process for the qualified clinical data registry-based reporting mechanism as the measures that may be reported via a qualified clinical data registry are not required to be measures found in the PORS measure set. Unfortunately, we will not receive measure information from clinical data

registries in time to develop the measure clusters needed to implement such a MAV process. Therefore, it would be difficult for CMS to determine appropriate measure clusters for the MAV process.

In summary, based on the comments received and for the reasons explained previously, we are finalizing the following criteria for an individual eligible professional to meet the criteria for satisfactory participation in a qualified clinical data registry for the 2016 PQRS payment adjustment:

For the 12-month 2016 PQRS payment adjustment reporting period, report at least 9 measures covering at least 3 NQS domains AND report each measure for at least 50 percent of the applicable patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted. Of the measures reported via a qualified clinical data registry, the eligible professional must report on at least 1 outcome measure; OR

For the 12-month 2016 PQRS payment adjustment reporting period, report at least 3 measures covering at least 1 NQS domain AND report each measure for at least 50 percent of the applicable patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted.

Tables 47 and 48 provide a summary of the final criteria for satisfactory reporting and satisfactory participation we discussed above for individual eligible professionals for the 2014 PQRS incentive and 2016 PQRS payment adjustment, respectively.

TABLE 47: Summary of Requirements for the 2014 PQRS Incentive: Individual Reporting Criteria for Satisfactory Reporting of Individual Quality Measures via Claims, Qualified Registries, and EHRs and Satisfactory Participation Criterion in Qualified Clinical Data Registries

Reporting Period	Measure Type	Reporting Mechanism	Satisfactory Reporting Criteria/Satisfactory Participation Criterion
12-month (Jan 1 — Dec 31)	Individual Measures	Claims	Report at least 9 measures covering at least 3 NQS domains, OR, if less than 9 measures covering at least 3 NQS domains apply to the eligible professional, report 1—8 measures covering 1—3 NQS domains, AND report each measure for at least 50 percent of the Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted.
			* For an eligible professional who reports fewer than 9 measures covering 3 NQS domains via the claims-based reporting mechanism, the eligible professional will be subject to the MAV process, which would allow us to determine whether an eligible professional should have reported quality data codes for additional measures and/or covering additional NQS domains.
12-month (Jan 1 — Dec 31)	Individual Measures	Qualified Registry	Report at least 9 measures covering at least 3 of the NQS domains, OR, if less than 9 measures covering at least 3 NQS domains apply to the eligible professional, report 1—8 measures covering 1-3 NQS domains for which there is Medicare patient data, AND report each measure for at least 50 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted.
			* For an eligible professional who reports fewer than 9 measures covering 3 NQS domains via the registry-based reporting mechanism, the eligible professional will be subject to the MAV process, which would allow us to determine whether an eligible professional should have reported on additional measures and/or measures covering additional NQS domains.
** 12-month (Jan 1 — Dec 31)	Individual Measures	Direct EHR product that is CEHRT and EHR data submission vendor that is CEHRT	Report 9 measures covering at least 3 of the NQS domains. If an eligible professional's CEHRT does not contain patient data for at least 9 measures covering at least 3 domains, then the eligible professional must report the measures for which there is Medicare patient data. An eligible professional must report on at least 1 measure for which there is Medicare patient data.
** 12-month (Jan 1 — Dec 31)	Measures Groups	Qualified Registry	Report at least 1 measures group, AND report each measures group for at least 20 patients, a majority of which much be Medicare Part B FFS patients.
** 6-month	Measures	Qualified	Report at least 1 measures group, AND report each measures group

Reporting Period	Measure Type	Reporting Mechanism	Satisfactory Reporting Criteria/Satisfactory Participation Criterion
(Jul 1 – Dec 31)	Groups	Registry	for at least 20 patients, a majority of which much be Medicare Part B FFS patients.
12-month (Jan 1 — Dec 31)	Measures selected by Qualified Clinical Data Registry	Qualified Clinical Data Registry	Report at least 9 measures covering at least 3 NQS domains AND report each measure for at least 50 percent of the eligible professional's applicable patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted. Of the measures reported via a qualified clinical data registry, the eligible professional must report on at least 1 outcome measure.

^{*}Subject to the MAV process.

TABLE 48: Summary of Requirements for the 2016 PQRS Payment Adjustment: Individual Reporting Criteria for Satisfactory Reporting of Individual Quality Measures via Claims, Registries, and EHRs and Satisfactory Participation Criterion in Qualified Clinical Data Registries

Reporting Period	Measure Type	Reporting Mechanism	Satisfactory Reporting Criteria/Satisfactory Participation Criterion
12-month (Jan 1 — Dec 31)	Individual Measures	Claims	Report at least 9 measures covering at least 3 NQS domains, OR, if less than 9 measures covering at least 3 NQS domains apply to the eligible professional, report 1—8 measures covering 1—3 NQS domains, AND report each measure for at least 50 percent of the Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted. * For an eligible professional who reports fewer than 9 measures covering 3 NQS domains via the claims-based reporting mechanism, the eligible professional will be subject to the MAV process, which would allow us to determine whether an eligible professional should have reported quality data codes for additional measures and/or covering additional NQS domains.
** 12-month (Jan 1 — Dec 31)	Individual Measures	Claims	Report at least 3 measures, OR, If less than 3 measures apply to the eligible professional, report 1— 2 measures*; AND Report each measure for at least 50 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate will not be counted.
12-month (Jan 1 — Dec 31)	Individual Measures	Qualified Registry	Report at least 9 measures covering at least 3 of the NQS domains, OR, if less than 9 measures covering at least 3 NQS domains apply to the eligible professional, report 1—8 measures covering 1-3 NQS domains for which there is Medicare patient data, AND report each

^{**} Finalized in the CY 2013 PFS final rule (see Table 91 at 77 FR 69194).

Reporting Period	Measure Type	Reporting Mechanism	Satisfactory Reporting Criteria/Satisfactory Participation Criterion
			measure for at least 50 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted.
			* For an eligible professional who reports fewer than 9 measures covering at least 3 NQS domains via the registry-based reporting mechanism, the eligible professional will be subject to the MAV process, which would allow us to determine whether an eligible professional should have reported on additional measures and/or measures covering additional NQS domains.
12-month (Jan 1 — Dec 31)	Individual Measures	Qualified Registry	Report at least 3 measures covering at least 1 of the NQS domains, OR, if less than 3 measures apply to the eligible professional, report 1—2 measures covering at least 1 NQS domain for which there is Medicare patient data, AND report each measure for at least 50 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted.
			* For an eligible professional who reports fewer than 3 measures covering 1 NQS domain via the registry-based reporting mechanism, the eligible professional will be subject to the MAV process, which would allow us to determine whether an eligible professional should have reported on additional measures.
** 12-month (Jan 1 — Dec 31)	Individual Measures	Direct EHR product that is CEHRT and EHR data submission vendor that is CEHRT	Report 9 measures covering at least 3 of the NQS domains. If an eligible professional's CEHRT does not contain patient data for at least 9 measures covering at least 3 domains, then the eligible professional must report the measures for which there is Medicare patient data. An eligible professional must report on at least 1 measure for which
** 12-month (Jan 1 — Dec 31)	Measures Groups	Qualified Registry	there is Medicare patient data. Report at least 1 measures group, AND report each measures group for at least 20 patients, a majority of which much be Medicare Part B FFS patients.
** 6-month (Jul 1 – Dec 31)	Measures Groups	Qualified Registry	Report at least 1 measures group, AND report each measures group for at least 20 patients, a majority of which much be Medicare Part B FFS patients.
12-month (Jan 1 — Dec 31)	Measures selected by Qualified Clinical Data Registry	Qualified Clinical Data Registry	Report at least 9 measures covering at least 3 NQS domains AND report each measure for at least 50 percent of the eligible professional's applicable patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted.
			Of the measures reported via a qualified clinical data registry, the

Reporting Period	Measure Type	Reporting Mechanism	Satisfactory Reporting Criteria/Satisfactory Participation Criterion
			eligible professional must report on at least 1 outcome measure.
12-month (Jan 1 — Dec 31)	Measures selected by Qualified Clinical Data Registry	Qualified Clinical Data Registry	Report at least 3 measures covering at least 1 NQS domain AND report each measure for at least 50 percent of the eligible professional's applicable patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted.

^{*}Subject to the MAV process.

7. Criteria for Satisfactory Reporting for the 2014 PQRS Incentive for Group Practices in the GPRO

For 2014, in accordance with §414.90(c)(3), eligible professionals that satisfactorily report data on PQRS quality measures are eligible to receive an incentive equal to 0.5 percent of the total estimated Medicare Part B allowed charges for all covered professional services furnished by the eligible professional or group practice during the applicable reporting period. We finalized criteria for the satisfactory reporting for group practices participating in the GPRO for the 2014 PQRS incentive in the CY 2013 PFS final rule with comment period (see Table 93, 77 FR 69195). In the CY 2014 PFS proposed rule, we proposed to change some of the criteria for satisfactory reporting for group practices under the GPRO using the registry and GPRO web interface reporting mechanisms (78 FR 43368).

Group practices may currently report PQRS quality measures data to meet the criteria for satisfactory reporting for the 2014 PQRS incentive via the registry, EHR, and GPRO web interface reporting mechanisms. First, for the 2014 PQRS incentive, we previously finalized the following criterion for the satisfactory reporting of PQRS quality measures via the GPRO web interface for group practices comprised of 25-99 eligible professionals: Report on all measures included in the web interface; AND populate data fields for the first 218 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 218, then report on 100 percent of assigned beneficiaries (77 FR 69195). To streamline the PQRS and eliminate reporting options that are largely unused, in the CY 2014 PPS proposed rule, we proposed to eliminate this criterion under the GPRO for the 2014 PQRS incentive.

^{**} Finalized in the CY 2013 PFS final rule (see Table 91 at 77 FR 69194).

As a result, group practices composed of 25-99 eligible professionals would no longer have the option to report PQRS quality measures using the GPRO web interface for the 2014 PQRS incentive (78 FR 43368). We solicited and received the following public comments on this proposal:

<u>Comment</u>: Several commenters opposed our proposal to eliminate the option for group practices comprised of 25-99 eligible professionals to report PQRS quality measures using the GPRO web interface for the 2014 PQRS incentive. The commenters request that, although there has been low participation in this reporting option, we keep this option for at least one more year. The commenters believe that group practices may increasingly use this option, particularly as the PQRS moves from an incentive-based to a program that solely provides payment adjustments.

Response: While we proposed to eliminate this reporting option due to low participation, we agree with the commenters. We understand that other commenters expressed similar concerns with our proposal to eliminate the option to report PQRS measures groups via registry, yet we are still finalizing our proposal to eliminate the option to report PQRS measures groups via registry for the 2014 PQRS incentive and 2016 PQRS payment adjustment. Unlike the option to report PQRS measures groups via registry, the option for group practices comprised of 25-99 eligible professionals to report PQRS quality measures using the GPRO web interface is relatively new as it was finalized in the CY 2013 PRS final rule with comment period (77 FR 69196). As such, we are willing to keep the option for group practices comprised of 25-99 eligible professionals to report PQRS quality measures using the GPRO web interface for the 2014 PQRS incentive to see whether PQRS participation using this reporting criterion will increase. Therefore, we are not finalizing our proposal to eliminate this GPRO reporting option.

However, we note that should we continue to see low participation in this reporting criterion, we may propose to eliminate this reporting criterion again in future rulemaking.

In the CY 2013 PFS final rule with comment period, for reporting under the GPRO using the registry-based reporting mechanism, we finalized the following criterion for the satisfactory reporting of PQRS quality measures for group practices composed of 2 or more eligible professionals for the 2014 PQRS incentive: Report at least 3 measures, AND report each measure for at least 80 percent of the group

practice's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate will not be counted (77 FR 69196). For the same reasons we proposed to increase the number of measures an individual eligible must report, as well as decrease the percentage threshold for individual eligible professionals reporting via registry for the 2014 PQRS incentive in the CY 2014 PFS proposed rule, we proposed the following modified criteria for the satisfactory reporting of individual quality measures under the GPRO for the registry-based reporting mechanism: Report at least 9 measures covering at least 3 of the NQS domains; AND report each measure for at least 50 percent of the group practice's applicable seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate will not be counted (78 FR 43368). We solicited and received the following public comments on this proposal:

<u>Comment</u>: The majority of commenters supported our proposal to decrease the percentage of patients that must be reported via registry from 80 percent to 50 percent. The commenters supported our proposal specifically because this threshold aligns with the option to report individual measures via the claims-based reporting mechanism.

Response: We appreciate the commenters' feedback and, based on the support received and for the reasons stated previously, we are finalizing this proposal for reducing the reporting threshold.

Therefore, for the 2014 PQRS incentive, a group practice reporting individual quality measures via registry will be required to report each measure for at least 50 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Please note, however, that as the program evolves, we anticipate increasing the reporting threshold again both for the registry-based reporting mechanism.

<u>Comment</u>: Several commenters supported our proposal to increase the number of measures to be reported via registry to 9, as requiring a group practice to report on more measures would better capture the quality of care provided by a group practice. However, while several commenters generally supported our proposal to increase the number of measures to be reported via registry, the commenters urged CMS to provide a more gradual approach to increasing the number of measures that must be reported via

registry. These commenters suggested requiring the reporting of either 4 measures covering at least 1 NQS domain, 5 measures covering at least 2 NQS domains, or 6 measures covering at least 2 NQS domains.

The majority of commenters opposed our proposal to increase the number of measures to be reported via registry from 3 to 9. Several of these commenters generally opposed any proposal that would increase the number of measures to be reported via registry from 3. Some of these commenters urged CMS not to increase the criteria for satisfactory reporting until participation in PQRS increases, as the commenters feared that increasing the criteria for satisfactory reporting in PQRS would discourage eligible professionals from participating in the PQRS. Still some of these commenters opposing this proposal noted that certain eligible professionals did not have 9 measures for which to report.

Response: We appreciate commenters' positive feedback, as well as suggested alternative reporting criteria. We understand the commenters' concerns opposing this proposal. However, we believe that it is important to collect data that provides a broad picture of the quality of care provided by a group practice, and, as discussed in section K of this final rule with comment period, such information will be used, in part, for the Value-based Payment Modifier to determine upward, downward, and neutral adjustments based on physician performance. So we believe it is important to raise the measure threshold from 3 measures covering 1 NQS domain to 9 measures covering 3 NQS domains. As we noted above and in the proposed rule (78 FR 43368), we believe that we have provided group practices with enough time to familiarize themselves with the reporting options for satisfactory reporting under the PQRS, particularly for the PQRS incentives.

For the commenters who urge us not to increase the satisfactory reporting criteria for the PQRS until participation in PQRS increases, we understand that, as discussed in this final rule below and in the 2011 PQRS and eRx Reporting Experience, participation in the PQRS has fluctuated around 25 percent among those eligible to participate in the PQRS. Indeed, it is one of our major goals to increase participation in the PQRS. While increasing the satisfactory reporting threshold for the 2014 PQRS incentive may deter or discourage eligible professionals from participating, we believe the increase we

proposed for the satisfactory reporting threshold will not significantly deter eligible professionals in group practices from participating in the PQRS. Also, we note that eligible professionals in group practices will be required to report PQRS quality measures data to meet the criteria for satisfactory reporting for the 2016 PQRS payment adjustment, the reporting periods of which run concurrently with the reporting periods for the 2014 PQRS incentive. Since eligible professionals will already be required to meet the criteria for satisfactory reporting for the 2016 PQRS payment adjustment, we believe these eligible professionals will also attempt to report for the 2014 PQRS incentive regardless of whether we increase the measure threshold from 3 measures covering 1 NQS domain to 9 measures covering 3 NQS domains.

But to addres the commenters' concerns about not having at least 9 PQRS measures covering 3 NQS domains for which to report via registry, we are modifying what we are finalizing to allow group practices to report fewer measures so that group practices who do not have at least 9 PQRS measures applicable to their practice. Specifically, if fewer than 9 measures covering less than 3 NQS domains apply to the group practice, a group practice must report 1-8 measures covering 1-3 NQS domains for which there is Medicare patient data. Given this change to the criterion, we will apply a MAV process, which will be triggered when a group practice reports on less than 9 measures. This is consistent with our practice for applying this process to the claims-based reporting option for individuals to report individual measures. For example, if a group practice reports on 8 measures covering 2 NQS domains, the MAV process will be triggered to determine whether a group practice could have reported on an additional measure and/or covering an additional domain.

The 2014 registry MAV process that will determine whether a group practice could have reported on more measures and/covering more NQS domains will be similar to the "clinical relation" test used in the 2013 claims MAV process. To get a better sense of how the 2014 registry MAV process will be implemented by CMS, a description of the "clinical relation" test in the current 2013 claims MAV process is available at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Downloads/2013_PQRS_MeasureApplicabilityValidation_Docs_030413.zip. Please note that we will post a guidance document on the 2014 registry MAV process, which will include a list

of the measure clusters that are used for the "clinical relation" test, prior to January 1, 2014 (the start of the 2014 reporting periods).

We believe modifying the reporting criterion will address commenters concerns, while still maintaining our general goal of increasing the measures reported to 9 measures covering 3 NQS domains. This also will increase the likelihood that more eligible professionals, including those in group practices, will be able to take advantage of this reporting option.

For the reasons stated above, we are finalizing the following criterion for group practices in the GPRO reporting individual PQRS quality measures via registry for the 2014 PQRS incentive: For the 12-month reporting period for the 2014 PQRS incentive, report at least 9 measures covering at least 3 of the NQS domains, OR, if less than 9 measures covering at least 3 NQS domains apply to the group practice, report 1—8 measures covering 1-3 NQS domains for which there is Medicare patient data, AND report each measure for at least 50 percent of the group practice's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted. For a group practice who reports fewer than 9 measures covering less than 3 NQS domains via the registry-based reporting mechanism, the group practice would be subject to the MAV process, which would allow us to determine whether a group practice should have reported on additional measures and/or measures covering additional NQS domains.

Third, under our authority under section 1848(m)(3)(C)(i) of the Act to select the measures for which a group practice must report, based on our desire to encourage the use of patient surveys to assess beneficiary experience of care and outcomes, we proposed to provide group practices composed of 25 or more eligible professionals with a new satisfactory reporting criterion that would include the option to complete the CG CAHPS survey along with reporting 6 other PQRS measures for purposes of meeting the criteria for satisfactory reporting for the 2014 PQRS incentive and 2016 PQRS payment adjustment (78 FR 43368).

We further proposed that the survey would be administered following the close of the PQRS registration period. We indicated that CMS would provide each group a detailed report about the results

of the survey. In addition, we proposed to assign beneficiaries to a group practice using the same assignment methodology that we use for the GPRO web interface (77 FR 69195). This method focuses on assigning beneficiaries to a group based on whether the group provided the plurality of primary care services. Because we proposed to assign beneficiaries to a group based on the provision of primary care services, we noted that this survey is not an appropriate option for groups of physicians (for example, such as a group of surgeons) that do not provide primary care services. In accordance with section 1848(m)(3)(C)(ii) of the Act, which requires the GPRO to provide for the use of a statistical sampling model, we propose that the survey would be administered by certified survey vendor on behalf of the group practice for a sample of group's assigned beneficiaries. As noted earlier, to complete this survey, a group practice must indicate its intent to report the CG CAHPS survey when it registers to participate in the PQRS via the GPRO.

Please note that the CAHPS survey measures only cover 1 NQS domain. To be consistent with other group practice reporting criteria we proposed to require the reporting of measures covering at least 3 NQS domains, we proposed that, unless a group practice is comprised of 100 or more eligible professionals and is participating in the PQRS via the GPRO web interface, if a group practice comprised of 25 of more eligible professionals reports the CAHPS measures via a certified survey vendor, the group practice would be required to report on at least 6 additional measures covering at least 2 NQS domains.

Specifically, we proposed the following criteria for satisfactory reporting for the 2014 PQRS incentive: For the 12-month reporting period for the 2014 PQRS incentive, report all CAHPS survey measures via a certified vendor, AND report at least 6 measures covering at least 2 of the NQS domains using the qualified registry, direct EHR product, EHR data submission vendor, or GPRO web interface reporting mechanisms (78 FR 43368).

We solicited and received the following public comments on our proposed criterion for the satisfactory reporting of data on these PQRS quality measures under the GPRO for the 2014 PQRS incentive:

<u>Comment</u>: Although one commenter supported the proposal to allow all group practices of 25 or more eligible professionals in the GPRO to report the CG CAHPS survey measures for the 2014 PQRS incentive, since the cost to do the survey will be at the practice's expense, the commenter appreciate CMS' proposal to make this optional for practices.

Response: We appreciate the commenter's response. Unfortunately, except for group practices comprised of 100 or more eligible professionals in the GPRO that are using the GPRO web interface reporting mechanism who must report the CG CAHPS measures (77 FR 69267) to meet the criteria for satisfactory reporting for the 2014 PQRS incentive, we cannot bear the cost of administering the CG CAHPS survey to group practices. However, in the interest of encouraging the administering and reporting of CG CAHPS data, we proposed this alternative reporting criterion for which group practices may use to meet the criteria for satisfactory reporting for the 2014 PQRS incentive. Since CMS cannot bear the cost of administering the CG CAHPS survey for these group practices, the reporting of CG CAHPS measures is optional for the purpose of meeting the criteria for satisfactory reporting for the 2014 PQRS incentive except for group practices comprised of 100+ eligible professionals who are reporting PQRS measures via the GPRO web interface.

Comment: Some commenters opposed our proposal to require the reporting of 6 measures covering at least 2 of the NQS domains using the qualified registry, direct EHR product, EHR data submission vendor, or GPRO web interface reporting mechanisms in addition to the CG CAHPS survey. Commenters felt this proposed criterion was too onerous, especially given the time and expense associated with administering the CG CAHPS survey.

Response: We understand the commenters' concerns with this proposal. However, we believe requiring the reporting of 6 measures covering at least 2 of the NQS domains using the qualified registry, direct EHR product, EHR data submission vendor, or GPRO web interface reporting mechanisms in addition to the CG CAHPS survey is fair. The CG CAHPS survey measure only satisfies the reporting of 1 NQS domain, while other group practice criteria we have established for the registry and EHR-based reporting mechanisms for the 2014 PQRS incentive require the reporting of measures in at least 3 NQS

domains to meet the criteria for satisfactory reporting for the 2014 PQRS incentive. In addition, we note that requiring the reporting of 6 measures in addition to the CG CAHPS survey would essentially require a group practice to report on 6 measures and 12 survey questions, for a total of 18 measures and questions. We note that this is the same number of measures (18) that we currently require group practices in the GPRO to report via the GPRO web interface. Based on the comments received and for the reasons stated previously, we are finalizing the following criterion for a group practice comprised of 25 or more eligible professionals who chooses to complete the CG CAHPS survey in conjunction with the qualified registry, direct EHR product, EHR data submission vendor, or GPRO web-interface reporting mechanisms: For the 12-month reporting period for the 2014 PQRS incentive, report all CAHPS survey measures via a certified vendor, AND report at least 6 measures covering at least 2 of the NQS domains using the qualified registry, direct EHR product, EHR data submission vendor, or GPRO web interface reporting mechanisms. We are modifying § 414.90(h) to indicate this reporting criterion.

8. Criteria for Satisfactory Reporting for the 2016 PQRS Payment Adjustment for Group Practices in the GPRO

This section addresses the certain proposals we made regarding criteria for satisfactory reporting for group practices in the GPRO for the 2016 PQRS payment adjustment using the registry, GPRO web interface, and certified survey vendor reporting mechanisms. In the CY 2013 PFS final rule with comment period, we finalized the same criteria for satisfactorily reporting data on quality measures for the 2016 PQRS payment adjustment that apply for the 2014 PQRS incentive for the PQRS GPRO (77 FR 69200). In the CY 2014 PFS proposed rule, we made three of the same proposals for the criteria for satisfactory reporting under the GPRO for the 2016 PQRS payment adjustment that we are proposed for the 2014 PQRS incentive (78 FR 43369).

Specifically, to coincide with our proposals for the 2014 PQRS incentive, we first proposed (78 FR 43369) to eliminate the following criterion for satisfactory reporting of PQRS quality measures via the GPRO web interface for group practices comprised of 25-99 eligible professionals: Report on all measures included in the web interface; AND populate data fields for the first 218 consecutively ranked

and assigned beneficiaries in the order in which they appear in the group's sample for each module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 218, then report on 100 percent of assigned beneficiaries. We solicited and received the following public comments on this proposal:

<u>Comment</u>: Several commenters opposed our proposal to eliminate the option for group practices comprised of 25-99 eligible professionals to report PQRS quality measures using the GPRO web interface for the 2014 PQRS incentive. The commenters request that, although there has been low participation in this reporting option, we keep this option for at least one more year. The commenters believe that group practices may increasingly use this option, particularly as the PQRS moves from an incentive-based to a program that solely provides payment adjustments.

Response: We appreciate the commenters' feedback and understand the commenters' concerns. Since we are not finalizing our proposal to eliminate this reporting criterion for the 2014 PQRS incentive, to coincide with the criterion established for the 2014 PORS incentive and for the same reasons we are not finalizing our proposal to remove this reporting criterion for the 2014 PQRS incentive, we are not finalizing our proposal to remove this reporting criterion. As we previously stated, although we proposed to eliminate this reporting criterion due to low participation, we are willing to keep the option for group practices comprised of 25-99 eligible professionals to report PQRS quality measures using the GPRO web interface for the 2014 PORS incentive to see whether PORS participation using this reporting criterion will increase. However, we note that should we continue to see low participation in this reporting criterion, we may propose to eliminate this reporting criterion again in future rulemaking. Based on the comments received and for the reasons previously stated, group practices of 25-99 eligible professionals have the option to use the following criterion for satisfactory reporting of PQRS quality measures via the GPRO web interface: Report on all measures included in the web interface; AND populate data fields for the first 218 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 218, then report on 100 percent of assigned beneficiaries.

Second, we proposed to remove the following criterion for satisfactory reporting via registry under the GPRO for the 2016 PQRS payment adjustment: Report at least 3 measures, AND report each measure for at least 80 percent of the group practice's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate will not be counted (78 FR 43369). By eliminating this option as proposed, a group practice reporting via registry would have been required to meet the same criteria for satisfactory reporting for the 2014 PQRS incentive as the 2016 PQRS payment adjustment. This would allow us to maintain consistent criteria for the 2016 PQRS payment adjustment and 2014 PQRS incentive. We solicited and received the following public comments on this proposal:

Comment: While several commenters supported our proposal to increase the number of measures to be reported via registry, these commenters generally did not support eliminating this reporting criterion. Other commenters expressed concern that there are still group practices who do not have 3 measures applicable to their practice. These commenters therefore suggested that this criterion be modified to require the reporting of only 1 measure covering 1 NQS domain for the 2016 PQRS payment adjustment, similar to the criterion that was finalized for the 2015 PQRS payment adjustment (77 FR 69200), as some commenters are concerned that there are still group practices who do not have 3 measures applicable to their practice.

Response: We understand the commenters' concerns regarding eliminating this reporting criterion. Although we still desire to move towards the reporting of more measures, we understand that eligible professionals may need another year to adjust to the reporting of additional measures. We believe it is pertinent to allow time for eligible professionals to adjust to the reporting of additional measures for purposes of the 2016 PQRS payment adjustment as opposed to the 2014 PQRS incentive, where forgoing reporting has no downward payment consequencee. Therefore, based on the concerns expressed by commenters, we are not finalizing our proposal to eliminate this reporting criterion for the 2016 PQRS payment adjustment, but as noted below, are further modifying the criterion in this final rule. We note,

however, that it is our intention to move towards the reporting of 9 measures covering at least 3 NQS domains for the 2017 PQRS payment adjustment.

To address commenters concerns and to coincide with the percentage reporting threshold we are finalizing for group practices who report individual measures via registry for the 2014 PQRS incentive, we are lowering the percentage threshold for the reporting of measures via registry for the 2016 PQRS payment adjustment from 80 to 50 percent. We believe this modification reduces reporting burden on group practices since they will be required to report on less patients. This further aligns with some the reporting criteria for the 2014 PQRS incentive criteria.

For the commenters who expressed concern that there are still group practices who do not have 3 measures applicable to their practice, we are finalizing another modification to allow eligible professionals to report 1-2 applicable measures. And consistent with the other final policies we are adopting, we will apply a registry MAV process for the 2016 PQRS payment adjustment. For purposes of this reporting criterion, the registry MAV process will be triggered when a group practice reports on less than 3 measures. For example, if a group practice reports on 1—2 measures, the MAV process will be triggered to determine whether a group practice could have reported on at least 3 measures covering 1 NQS domain. We believe implementing this change to the criterion for the 2016 PQRS payment adjustment will help to alleviate commenters' concerns that certain group practices may not have a sufficient number of measures to report covering a sufficient amount of NQS domains.

This registry MAV process that will determine whether a group practice could have reported on more measures will be similar to the "clinical relation" test used in the 2013 claims MAV process. To get a better sense of how the registry MAV process for the 2016 PQRS payment adjustment will be implemented by CMS, a description of the "clinical relation" test in the current 2013 claims MAV process is available at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Downloads/2013_PQRS_MeasureApplicabilityValidation_Docs_030413.zip. Please note that we will post a guidance document on the registry MAV process for the 2016 PQRS payment

adjustment, which will include a list of the measure clusters that are used for the "clinical relation" test, prior to January 1, 2014 (the start of the 2014 reporting periods).

In summary, we are finalizing in the following criterion for satisfactory reporting via registry under the GPRO for the 2016 PQRS payment adjustment: For the 12-month reporting period for the 2016 PQRS payment adjustment, report at least 3 measures covering at least 1 of the NQS domains, OR, if less than 3 measures apply to the group practice, report 1—2 measures covering at least 1 NQS domain for which there is Medicare patient data, AND report each measure for at least 50 percent of the group practice's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted. For a group practice who reports fewer than 3 measures via the registry-based reporting mechanism, the group practice would be subject to the MAV process, which would allow us to determine whether a group practice should have reported on additional measures.

Third, to coincide with criterion we are finalizing for the 2014 PQRS incentive, we proposed (78 FR 43369) the following criterion for satisfactory reporting of measures via registry under the GPRO for the 2016 PQRS payment adjustment: Report at least 9 measures covering at least 3 of the National Quality Strategy domains, and report each measure for at least 50 percent of the group practice's applicable patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate will not be counted.

<u>Comment</u>: Several commenters generally supported our proposal to align the satisfactory reporting criteria for the 2014 PQRS incentive with the satisfactory reporting criteria for the 2016 PQRS payment adjustment.

Response: We appreciate the commenters' support. However, given that we are making certain changes to address concerns raised above and with regard to the 2014 incentive about increasing the number of measures to 9 and whether eligible professionals have enough applicable measures to report to take advantage of this reporting criterion, we are finalizing a modification of the criterion that was proposed for the satisfactory reporting of measures via registry under the GPRO for the 2014 PQRS

incentive. This will also help to meet our goal of alignment under the program where possible with regard to various reporting criteria.

Specifically, we are finalizing the following criterion for satisfactory reporting via registry under the GPRO for the 2016 PQRS payment adjustment: Report at least 9 measures covering at least 3 of the NQS domains, OR, if less than 9 measures covering at least 3 NQS domains apply to the group practice, report 1—8 measures covering 1-3 NQS domains for which there is Medicare patient data, AND report each measure for at least 50 percent of the group practice's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted. For a group practice who reports fewer than 9 measures covering less than 3 NQS domains via the registry-based reporting mechanism, the group practice would be subject to the MAV process, which would allow us to determine whether a group practice should have reported on additional measures and/or measures covering additional NQS domains.

Fourth, consistent with the proposal we made to provide group practices comprised of 25 or more eligible professionals with a new satisfactory reporting criterion that would include the option to complete the CG CAHPS survey along with reporting 6 other PQRS measures for purposes of meeting the criteria for satisfactory reporting for the 2014 PQRS incentive, we also proposed the same criterion for purposes of meeting the criteria for satisfactory reporting for the 2016 PQRS payment adjustment. Specifically, we proposed the following criteria for satisfactory reporting for the 2016 PQRS payment adjustment: For the 12-month reporting period for the 2016 PQRS payment adjustment, report all CAHPS survey measures via a certified vendor, AND report at least 6 measures covering at least 2 of the NQS domains using the qualified registry, direct EHR product, EHR data submission vendor, or GPRO web interface reporting mechanisms. As noted earlier, to complete this survey, a group practice must indicate its intent to report the CG CAHPS survey when it registers to participate in the PQRS via the GPRO (78 FR 43369). We solicited and received the following public comments on this proposed criterion:

<u>Comment</u>: Although one commenter supported the proposal to allow all group practices of 25 or more eligible professionals in the GPRO to report the CG CAHPS survey measures, since the cost to do

the survey will be at the practice's expense, the commenter appreciates CMS' proposal to make this optional for practices.

Response: We appreciate the commenter's response. However, although this reporting criterion is generally optional for group practices of 25 or more eligible professionals, please note that completion of the CG CAHPS survey it not optional for all group practices participating under the GPRO for the 2016 PQRS payment adjustment. As we stated in the CY 2013 PFS final rule with comment period, all group practices comprised of 100 or more eligible professionals in the GPRO that are using the GPRO web interface reporting mechanism must report the CG CAHPS measures (77 FR 69267) to meet the criteria for satisfactory reporting for the 2014 PQRS incentive. Since, as finalized in the CY 2013 PFS final rule with comment period (77 FR 69200), a group practice may meet the criteria for satisfactory reporting for the 2016 PQRS payment adjustment by meeting the criteria for satisfactory reporting for the 2014 PQRS incentive, all group practices comprised of 100 or more eligible professionals in the GPRO that are using the GPRO web interface reporting mechanism must also report the CG CAHPS measures (77 FR 69267) to meet the criteria for satisfactory reporting for the 2016 PQRS payment adjustment. Because we are requiring these group practices to report the CG CAHPS survey measures, we noted that CMS would bear the cost of administering the survey.

Nonetheless, we are pleased with the commenter's support with making reporting of the CG CAHPS survey measures optional for the 2014 PQRS incentive. We understand that it is a considerable expense to administer the CG CAHPS survey. Since CMS cannot bear the cost of administering the CG CAHPS survey for these group practices, the reporting of CG CAHPS measures is optional for the purpose of meeting the criteria for satisfactory reporting for the 2016 PQRS payment adjustment except for group practices comprised of 100+ eligible professionals who are reporting PQRS measures via the GPRO web interface.

<u>Comment</u>: Some commenters opposed our proposal to require the reporting of 6 measures covering at least 2 of the NQS domains using the qualified registry, direct EHR product, EHR data submission vendor, or GPRO web interface reporting mechanisms in addition to the CG CAHPS survey.

Commenters felt this proposed criterion was too onerous, especially given the time and expense associated with administering the CG CAHPS survey.

Response: We understand the commenters' concerns with this proposal. However, we believe requiring the reporting of 6 measures covering at least 2 of the NQS domains using the qualified registry, direct EHR product, EHR data submission vendor, or GPRO web interface reporting mechanisms in addition to the CG CAHPS survey is fair. The CG CAHPS survey measure only satisfies the reporting of 1 NQS domain, while most other group practice criteria we have established for the registry and EHRbased reporting mechanisms require the reporting of measures in at least 3 NOS domains to meet the criteria for satisfactory reporting for the 2016 PQRS payment adjustment. In addition, we note that requiring the reporting of 6 measures in addition to the CG CAHPS survey would essentially require a group practice to report on 6 measures and 12 survey questions, for a total of 18 measures and questions. We note that this is the same number of measures (18) that we currently require group practices in the GPRO to report via the GPRO web interface. Based on the comments received and for the reasons stated previously, we are finalizing the following criterion – which is identical to the criterion finalized for the 2014 PQRS incentive – for a group practice who chooses to complete the CG CAHPS survey in conjunction with the qualified registry, direct EHR product, EHR data submission vendor, or GPRO webinterface reporting mechanisms for the 2016 PQRS payment adjustment: For the 12-month reporting period for the 2014 PORS incentive, report all CAHPS survey measures via a certified vendor, AND report at least 6 measures covering at least 2 of the NQS domains using the qualified registry, direct EHR product, EHR data submission vendor, or GPRO web interface reporting mechanisms

Tables 49 and 50 provide a summary of our final criteria for the satisfactory reporting of data on PQRS quality measures via the GPRO for the 2014 PQRS incentive and 2016 PQRS payment adjustment. Please note that we are adding paragraph §414.90(h)(5) to specify the criteria for the satisfactory reporting of data on PQRS quality measures via the GPRO for the 2014 PQRS incentive as described in Table 49, and we are adding paragraph §414.90(j)(5) to specify the criteria for the satisfactory reporting

of data on PQRS quality measures via the GPRO for the 2016 PQRS payment adjustment as described in Table 50.

TABLE 49: Summary of Final Requirements for the 2014 PQRS Incentive: Criteria for Satisfactory Reporting of Data on PQRS Quality Measures via the GPRO

Reporting Period	Reporting Mechanism	Group Practice Size	Proposed Reporting Criterion
** 12-month (Jan 1 — Dec 31)	GPRO Web interface	25-99 eligible professiona ls	Report on all measures included in the web interface; AND Populate data fields for the first 218 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 218, then report on 100 percent of assigned beneficiaries.
** 12-month (Jan 1 — Dec 31)	GPRO Web interface	100+ eligible professiona ls	Report on all measures included in the web interface; AND Populate data fields for the first 411 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 411, then report on 100 percent of assigned beneficiaries. In addition, the group practice must also report all CG CAHPS survey measures via certified survey vendor.
12-month (Jan 1 — Dec 31)	Qualified Registry	2 + eligible professiona ls	Report at least 9 measures covering at least 3 of the NQS domains, OR, if less than 9 measures covering at least 3 NQS domains apply to the group practice, report 1—8 measures covering 1-3 NQS domains for which there is Medicare patient data, AND report each measure for at least 50 percent of the group practice's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted. For a group practice who reports fewer than 9 measures covering at least 3 NQS domains via the registry-based reporting mechanism, the group practice will be subject to the MAV process, which would allow us to determine whether a group practice should have reported on additional measures and/or measures covering additional NQS domains.
** 12-month (Jan 1 — Dec 31)	Direct EHR product that is CEHRT/EHR data submission vendor that is CEHRT	2+ eligible professiona ls	Report 9 measures covering at least 3 of the NQS domains. If a group practice's CEHRT does not contain patient data for at least 9 measures covering at least 3 domains, then the group practice must report the measures for which there is Medicare patient data. A group practice must report on at least 1 measure for which there is Medicare patient data.

12-month (Jan 1 — Dec 31	CMS-certified survey vendor + qualified registry, direct EHR product, EHR data submission vendor, or GPRO web interface	25+ eligible professiona ls	Report all CG CAHPS survey measures via a CMS-certified survey vendor, AND report at least 6 measures covering at least 2 of the NQS domains using a qualified registry, direct EHR product, EHR data submission vendor, or GPRO web interface.
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TABLE 50: Summary of Final Requirements for the 2016 PQRS Payment Adjustment: Criteria for Satisfactory Reporting of Data on PQRS Quality Measures via the GPRO

Reporting Period	Reporting Mechanism	Group Practice Size	Proposed Reporting Criterion
** 12-month (Jan 1 — Dec 31)	GPRO Web interface	25-99 eligible professiona ls	Report on all measures included in the web interface; AND Populate data fields for the first 218 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 218, then report on 100 percent of assigned beneficiaries.
** 12-month (Jan 1 — Dec 31)	GPRO Web interface	100+ eligible professiona ls	Report on all measures included in the web interface; AND Populate data fields for the first 411 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 411, then report on 100 percent of assigned beneficiaries. In addition, the group practice must report all CG CAHPS survey measures via certified survey vendor.
12-month (Jan 1 — Dec 31)	Qualified Registry	2 + eligible professiona ls	Report at least 9 measures covering at least 3 of the NQS domains, OR, if less than 9 measures covering at least 3 NQS domains apply to the group practice, report 1—8 measures covering 1-3 NQS domains for which there is Medicare patient data, AND report each measure for at least 50 percent of the group practice's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted. For a group practice who reports fewer than 9 measures via the registry-based reporting mechanism, the group practice would be subject to the MAV process, which would allow us to determine whether a group practice should have reported on additional measures and/or measures covering additional NQS domains.

^{*}Subject to the Measure Application Validity (MAV) process.

** Criteria finalized in the CY 2013 PFS final rule (77 FR 69200).

12-month (Jan 1 — Dec 31)	Qualified Registry	2 + eligible professiona ls	Report at least 3 measures covering at least 1 of the NQS domains, OR, if less than 3 measures covering 1 NQS domain apply to the group practice, report 1—2 measures covering 1 NQS domain for which there is Medicare patient data, AND report each measure for at least 50 percent of the group practice's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted. For a group practice who reports fewer than 3 measures covering 1 NQS domain via the registry-based reporting mechanism, the group practice would be subject to the MAV process, which would allow us to determine whether a group practice should have reported on additional measures.
** 12-month (Jan 1 — Dec 31)	Direct EHR product that is CEHRT/EHR data submission vendor that is CEHRT	2+ eligible professiona ls	Report 9 measures covering at least 3 of the NQS domains. If a group practice's CEHRT does not contain patient data for at least 9 measures covering at least 3 domains, then the group practice must report the measures for which there is Medicare patient data. A group practice must report on at least 1 measure for which there is Medicare patient data.
12-month (Jan 1 — Dec 31	CMS-certified survey vendor + qualified registry, direct EHR product, EHR data submission vendor, or GPRO web interface	25+ eligible professiona ls	Report all CG CAHPS survey measures via a CMS-certified survey vendor, AND report at least 6 measures covering at least 2 of the NQS domains using a qualified registry, direct EHR product, EHR data submission vendor, or GPRO web interface.

9. Statutory Requirements and Other Considerations for the Selection of PQRS Quality Measures for Meeting the Criteria for Satisfactory Reporting for 2014 and Beyond for Individual Eligible Professionals and Group Practices

CMS underwent an annual Call for Measures that solicited new measures from the public for possible inclusion in the PQRS for 2014 and beyond. During the Call for Measures, we requested measures for inclusion in PQRS that meet the following statutory and non-statutory criteria.

^{*}Subject to the Measure Application Validity (MAV) process.

** Criteria finalized in the CY 2013 PFS final rule (77 FR 69200).

Sections 1848(k)(2)(C) and 1848(m)(3)(C)(i) of the Act, respectively, govern the quality measures reported by individual eligible professionals and group practices reporting under the PQRS. Under section 1848(k)(2)(C)(i) of the Act, the PQRS quality measures shall be such measures selected by the Secretary from measures that have been endorsed by the entity with a contract with the Secretary under section 1890(a) of the Act (currently, that is the National Quality Forum, or NQF). However, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the NQF, section 1848(k)(2)(C)(ii) of the Act authorizes the Secretary to specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary, such as the AQA alliance. In light of these statutory requirements, we believe that, except in the circumstances specified in the statute, each PQRS quality measure must be endorsed by the NQF. Additionally, section 1848(k)(2)(D) of the Act requires that for each PQRS quality measure, "the Secretary shall ensure that eligible professionals have the opportunity to provide input during the development, endorsement, or selection of measures applicable to services they furnish."

The statutory requirements under section 1848(k)(2)(C) of the Act, subject to the exception noted previously, require only that the measures be selected from measures that have been endorsed by the entity with a contract with the Secretary under section 1890(a) of the Act (that is, the NQF) and are silent for how the measures that are submitted to the NQF for endorsement were developed. The basic steps for developing measures applicable to physicians and other eligible professionals prior to submission of the measures for endorsement may be carried out by a variety of different organizations. We do not believe there needs to be any special restrictions on the type or make-up of the organizations carrying out this basic process of development of physician measures, such as restricting the initial development to physician-controlled organizations. Any such restriction would unduly limit the basic development of quality measures and the scope and utility of measures that may be considered for endorsement as voluntary consensus standards for purposes of the PQRS.

In addition to section 1848(k)(2)(C) of the Act, section 1890A of the Act, which was added by section 3014(b) of the Affordable Care Act, requires that the entity with a contract with the Secretary under section 1890(a) of the Act (currently, that is the NQF) convene multi-stakeholder groups to provide input to the Secretary on the selection of certain categories of quality and efficiency measures. These categories are described in section 1890(b)(7)(B) of the Act, and include such measures as the quality measures selected for reporting under the PQRS. Under section 3014 of the Affordable Care Act, the NQF convened multi-stakeholder groups by creating the Measure Applications Partnership (MAP). Section 1890(A)(a) of the Act requires that the Secretary establish a pre-rulemaking process in which the Secretary must make publicly available by December 1st of each year a list of the quality and efficiency measures that the Secretary is considering for selection through rulemaking for use in the Medicare program. The NQF must provide CMS with the MAP's input on selecting measures by February 1st of each year. The list of measures under consideration for 2013 is available at http://www.qualityforum.org/map/.

As we noted above, section 1848(k)(2)(C)(ii) of the Act provides an exception to the requirement that the Secretary select measures that have been endorsed by the entity with a contract under section 1890(a) of the Act (that is, the NQF). We may select measures under this exception if there is a specified area or medical topic for which a feasible and practical measure has not been endorsed by the entity, as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We requested that stakeholders apply the following considerations when submitting measures for possible inclusion in the PQRS measure set:

- High impact on healthcare.
- Measures that are high impact and support CMS and HHS priorities for improved quality and efficiency of care for Medicare beneficiaries.
 - Measures that address gaps in the quality of care delivered to Medicare beneficiaries.
 - Address Gaps in the PQRS measure set.

• Measures impacting chronic conditions (chronic kidney disease, diabetes mellitus, heart failure, hypertension and musculoskeletal).

- Measures applicable across care settings (such as, outpatient, nursing facilities, domiciliary, etc.).
- Broadly applicable measures that could be used to create a core measure set required of all participating eligible professionals.
- Measures groups that reflect the services furnished to beneficiaries by a particular specialty.
 10. PQRS Quality Measures

Taking into consideration the statutory and non-statutory criteria we described previously, this section contains our proposals for the inclusion or removal of measures in PQRS for 2014 and beyond. We are classifying all measures against six domains based on the NQS's six priorities, as follows:

- (1) <u>Person and Caregiver-Centered Experience and Outcomes.</u> These are measures that reflect the potential to improve patient-centered care and the quality of care delivered to patients. They emphasize the importance of collecting patient-reported data and the ability to impact care at the individual patient level, as well as the population level through greater involvement of patients and families in decision making, self-care, activation, and understanding of their health condition and its effective management.
- (2) <u>Patient Safety</u>. These are measures that reflect the safe delivery of clinical services in both hospital and ambulatory settings and include processes that would reduce harm to patients and reduce burden of illness. These measures should enable longitudinal assessment of condition-specific, patient-focused episodes of care.
- (3) <u>Communication and Care Coordination</u>. These are measures that demonstrate appropriate and timely sharing of information and coordination of clinical and preventive services among health professionals in the care team and with patients, caregivers, and families to improve appropriate and timely patient and care team communication.

(4) <u>Community/Population Health</u>. These are measures that reflect the use of clinical and preventive services and achieve improvements in the health of the population served. These are outcome-focused and have the ability to achieve longitudinal measurement that will demonstrate improvement or lack of improvement in the health of the US population.

- (5) <u>Efficiency and Cost Reduction</u>. These are measures that reflect efforts to significantly improve outcomes and reduce errors. These measures also impact and benefit a large number of patients and emphasize the use of evidence to best manage high priority conditions and determine appropriate use of healthcare resources.
- (6) <u>Effective Clinical Care</u>. These are measures that reflect clinical care processes closely linked to outcomes based on evidence and practice guidelines.

Please note that the PQRS quality measure specifications for any given PQRS quality measure may differ from specifications for the same quality measure used in prior years. For example, for the PQRS quality measures that were selected for reporting in 2013 and beyond, please note that detailed measure specifications, including the measure's title, for the individual PQRS quality measures for 2013 and beyond may have been updated or modified during the NQF endorsement process or for other reasons. In addition, due to our desire to align measure titles with the measure titles that are finalized for 2013, 2014, 2015, and potentially subsequent years of the EHR Incentive Program, we note that the measure titles for measures available for reporting via EHRs may change from year to year. We note that the EHR Incentive Program has updated its measure titles to include version numbers, and these version numbers are referenced in the tables containing the final PQRS measures set below. Please note that any changes reflected below are not substantive. We will continue to work toward complete alignment, where possible, of measure specifications across programs, and do so in both rulemaking and subregulatory communication, as applicable, including through guidance such as in the detailed quality measure specifications PQRS publishes each year at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/index.html.

Through NOF's measure maintenance process, NOF endorsed measures are sometimes updated to incorporate changes that we believe do not substantively change the nature of the measure. Examples of such changes could be updated diagnosis or procedure codes or changes to exclusions to the patient population or definitions. We believe these types of maintenance changes are distinct from more substantive changes to measures that result in what are considered new or different measures, and that they do not trigger the same agency obligations under the Administrative Procedure Act. In the CY 2013 PFS final rule with comment period, we finalized our proposal providing that if the NQF updates an endorsed measure that we have adopted for the PORS in a manner that we consider to not substantively change the nature of the measure, we would use a subregulatory process to incorporate those updates to the measure specifications that apply to the program (77 FR 69207). We believe this adequately balances our need to incorporate non-substantive NQF updates to NQF-endorsed measures in the most expeditious manner possible, while preserving the public's ability to comment on updates that so fundamentally change an endorsed measure that it is no longer the same measure that we originally adopted. We also noted that the NQF process incorporates an opportunity for public comment and engagement in the measure maintenance process. We will revise the Specifications Manual and post notices to clearly identify the updates and provide links to where additional information on the updates can be found. Updates will also be available on the CMS PQRS website at http://www.cms.gov/Medicare/Quality- Initiatives-Patient-Assessment-Instruments/PQRS/index.html.

Additionally, eligible professionals and registry vendors should be aware that the 2014 Physician Quality Reporting System (PQRS) Claims/Registry Measure Specifications Manual and other supporting documentation may be published with placeholder quality-data codes (represented as GXXXX) in a subset of measures' numerator options. PQRS participants should note that these placeholder codes should not be submitted and will not count toward satisfactory reporting. In the event the specifications are published with the placeholder codes, we will revise the measure specifications and post notices to clearly identify the updates and provide links to where additional information on the updates can be found.

Updates will also be available on the CMS PQRS website at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/index.html.

For the PQRS EHR measures that are also reportable under the EHR Incentive Program (that is, electronically specified clinical quality measures), please note that the updates to these measures will be provided on the EHR Incentive Program website. We understand that the EHR Incentive Program may accept versions of electronically specified clinical quality measures that may be outdated. We proposed that for purposes of the PQRS, eligible professionals must report the most recent, updated version of a clinical quality measure (78 FR 43371). We solicited and received no public comment on this proposal. However, we are not finalizing this proposal. To avoid confusion on which measure version to report for the PQRS, rather than redirecting eligible professionals to the EHR Incentive Program website, although actual measure specifications will be provided on the EHR Incentive Program website, the electronic measure version that must be reported under the PQRS for a specific year will be found in the Measure Specifications List updated for that year. For example, for purposes of reporting clinical quality measures that are electronically specified during the PQRS reporting periods that occur in 2014, we would only accept the version of clinical quality measures that will be found in the 2014 Measure Specifications List, which will be made available at the PQRS website at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/index.html. However, please note that the 2014 PQRS Measures List will to the EHR Incentive Program's website for the measure specifications for the 2014 EHR measures.

We also understand, for purposes of the EHR Incentive Program, that once direct EHR products and EHR data submission vendors are issued a 2014 Edition certification for clinical quality measures, they will not necessarily be required to have such technology retested and recertified against the most recent, updated version of a clinical quality measure when such versions are made available. We proposed that for purposes of PQRS, however, that the eligible professional's direct EHR product or EHR data submission vendor must be tested and certified to the most updated, recent versions of electronically specified clinical quality measures for that year (78 FR 43371-43372). We solicited but received no

public comment on this proposal to require eligible professionals to use a direct EHR product or EHR data submission vendor that has been tested and certified to the most recent, updated version of the clinical quality measure's electronic specifications for PQRS purposes. However, we are not finalizing this proposal. Instead, for purposes of PQRS, the eligible professional's direct EHR product or EHR data submission vendor must be tested and certified to the versions of electronically specified clinical quality measures listed in the Measure Specifications List for the particular program year. For example, for purposes of reporting clinical quality measures that are electronically specified during the PQRS reporting periods that occur in 2014, we would only accept the reporting of clinical quality measures from direct EHR products or EHR data submission vendors that have been tested and certified to versions of the electronic specifications that will be found in the 2014 PQRS Measure Specifications List that will be released following the display of this final rule with comment period. Since the PORS Measure Specifications List is not typically released until late November/December of the year prior to the January 1 start of the reporting periods for a particularly year, we understand that vendors may be concerned with having enough time to update their systems with the most recent measure specifications in time prior to the start of the year. Please note that, unless there are errors discovered in updated electronic measure specifications, the PQRS intends to use the most recent, updated versions of electronically specified clinical quality measures for that year. For example, for 2014, the PQRS will accept the June 2013 versions of electronically specified clinical quality measures under the EHR Incentive Program, except for the following measure – CMS140v2, Breast Cancer Hormonal Therapy for Stage IC-IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer (NQF 0387). As a substantive error which would result in a, erroneous zero percent performance rate when reported this measure was discovered in the June 2013 version of this electronically specified clinical quality measure, the PQRS will require the use of the prior, December 2012 version of this measure, which is CMS140v1. a. Individual PQRS Measures and Measures within Measures Groups Available for Reporting for 2014

- a. Individual PQRS Measures and Measures within Measures Groups Available for Reporting for 2014 and Beyond
- (1) PQRS Core Measures Available for Reporting for 2014 and Beyond

In the CY 2013 PFS final rule with comment period, we finalized the HHS Million Hearts Measures as a recommended set of core measures for which we encourage eligible professionals to report in PQRS (77 FR 69209). In addition to the HHS Million Hearts Measures we previously finalized, we proposed to include the measures specified in the EHR Incentive Program as additional recommended core measures for 2014 and beyond (78 FR 43372-43378, Table 28). These additional proposed recommended core measures were also finalized as recommended core measures in the EHR Incentive Program for 2014. Therefore, due to our desire to align with the recommended measures available under the EHR Incentive Program, we proposed the additional recommended measures specified in Table 51 for 2014 and beyond. We solicited and received the following public comment on this proposal:

<u>Comment</u>: Several commenters generally supported our proposal to align, when possible, the clinical quality measures found under the PQRS and the clinical quality measures found under the EHR Incentive Program.

Response: We appreciate the commenters' general support in aligning measures under the PQRS and the EHR Incentive Program. In response to the comment and for the reasons we discussed above, we are finalizing our proposal to add these measures as recommended core measures under the PQRS for 2014 and beyond. Table 51 shows the final measures classified as the PQRS recommended core measures for 2014 and beyond.

TABLE 51: Physician Quality Reporting System Recommended Core Measures for 2014 and Beyond

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
0002/ 66 **	146v2	Efficiency and Cost Reduction	Appropriate Testing for Children with Pharyngitis: Percentage of children 2-18 years of age who were diagnosed with pharyngitis, ordered an antibiotic and received a group A streptococcus (strep) test for the episode	NCQA		X	X			MU2
0018/ 236 *	165v2	Effective Clinical Care	Controlling High Blood Pressure: Percentage of patients 18-85 years of age who had a diagnosis of hypertension and whose blood pressure was adequately controlled (<140/90 mmHg) during the measurement period.	NCQA	X	X	X	X	X	MU2 ACO Million Hearts
0022/ 238 *	156v2	Patient Safety	Use of High-Risk Medications in the Elderly: Percentage of patients 66 years of age and older who were ordered high-risk medications. Two rates are reported. a. Percentage of patients who were ordered at least one high-risk medication. b. Percentage of patients who were ordered at least two different high-risk medications.	NCQA			X			MU2

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
0024/ 239 **	155v2	Community/Population Health	Weight Assessment and Counseling for Nutrition and Physical Activity for Children and Adolescents: Percentage of patients 3-17 years of age who had an outpatient visit with a Primary Care Physician (PCP) or Obstetrician/Gynecologist (OB/GYN) and who had evidence of the following during the measurement period. Three rates are reported. - Percentage of patients with height, weight, and body mass index (BMI) percentile documentation - Percentage of patients with counseling for nutrition - Percentage of patients with counseling for physical activity	NCQA			X			MU2
0028/ 226 *	138v2	Community/Population Health	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: Percentage of patients 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user	AMA- PCPI	X	X	X	X	X	MU2 ACO Million Hearts
0033/ 310 **	153v2	Community/ Population Health	Chlamydia Screening for Women: Percentage of women 16-24 years of age who were identified as sexually active and who had at least one test for chlamydia during the measurement period	NCQA			X			MU2
0036/ 311 **	126v2	Effective Clinical Care	Use of Appropriate Medications for Asthma: Percentage of patients 5-64 years of age who were identified as having persistent asthma and were appropriately prescribed medication during the measurement period	NCQA			X			MU2

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description [‡]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
0038/ 240 **	117v2	Community/Population Health	Childhood Immunization Status: Percentage of children 2 years of age who had four diphtheria, tetanus and acellular pertussis (DTaP); three polio (IPV), one measles, mumps and rubella (MMR); three H influenza type B (HiB); three hepatitis B (Hep B); one chicken pox (VZV); four pneumococcal conjugate (PCV); one hepatitis A (Hep A); two or three rotavirus (RV); and two influenza (flu) vaccines by their second birthday	NCQA			X			MU2
0052/ 312 *	166v3	Efficiency and Cost Reduction	Use of Imaging Studies for Low Back Pain: Percentage of patients 18-50 years of age with a diagnosis of low back pain who did not have an imaging study (plain X-ray, MRI, CT scan) within 28 days of the diagnosis.	NCQA			X			MU2
0069/ 65 **	154v2	Efficiency and Cost Reduction	Appropriate Treatment for Children with Upper Respiratory Infection (URI): Percentage of children 3 months-18 years of age who were diagnosed with upper respiratory infection (URI) and were not dispensed an antibiotic prescription on or three days after the episode	NCQA		X	X			MU2

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
0108/ N/A **	136v3	Effective Clinical Care	ADHD: Follow-Up Care for Children Prescribed Attention-Deficit/Hyperactivity Disorder (ADHD) Medication: Percentage of children 6-12 years of age and newly dispensed a medication for attention-deficit/hyperactivity disorder (ADHD) who had appropriate follow-up care. Two rates are reported. a. Percentage of children who had one follow-up visit with a practitioner with prescribing authority during the 30-Day Initiation Phase. b. Percentage of children who remained on ADHD medication for at least 210 days and who, in addition to the visit in the Initiation Phase, had at least two additional follow-up visits with a practitioner within 270 days (9 months) after the Initiation Phase ended.	NCQA			X			MU2
0418/ 134 * **	2v3	Community/Population Health	Preventive Care and Screening: Screening for Clinical Depression and Follow-Up Plan: Percentage of patients aged 12 years and older screened for clinical depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen.	CMS	X	X	X	X		MU2 ACO

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
0419/ 130 *	68v3	Patient Safety	Documentation of Current Medications in the Medical Record: Percentage of visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list <u>must</u> include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND <u>must</u> contain the medications' name, dosage, frequency and route of administration.	CMS	X	X	X		X	MU2
0421/ 128 *	69v2	Community/Population Health	Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up: Percentage of patients aged 18 years and older with a documented BMI during the current encounter or during the previous 6 months AND when the BMI is <u>outside of normal parameters</u> , a follow-up plan is documented during the encounter or during the previous 6 months of the encounter Normal Parameters: Age 65 years and older BMI ≥ 23 and < 30; Age 18 − 64 years BMI ≥ 18.5 and < 25	CMS	X	X	X	X	X	MU2 ACO
N/A/ N/A **	75v2	Effective Clinical Care	Children Who Have Dental Decay or Cavities: Percentage of children, age 0-20 years, who have had tooth decay or cavities during the measurement period	CMS			X			MU2
N/A/ N/A *	50v2	Communication and Care Coordination	Closing the referral loop: receipt of specialist report: Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred	CMS			X			MU2

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description [‡]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
N/A/	90v3	Person and Caregiver-	Functional Status Assessment for Complex	CMS			X			MU2
N/A		Centered Experience and	Chronic Conditions: Percentage of patients aged 65							
*		Outcomes	years and older with heart failure who completed							
			initial and follow-up patient-reported functional status							
			assessments							

^{*} Recommended Adult Core CQMs for eligible professionals

^{**} Recommended Pediatric Core CQMs for eligible professionals

[¥] Titles and descriptions in this table are aligned with the 2014 Physician Quality Reporting System Claims and Qualified Registry measure titles and descriptions, and may differ based on reporting mechanism within PQRS. Additionally, there may be tittle and description variations for the same measure across other quality reporting programs. Please reference the National Quality Forum (NQF) and Physician Quality Reporting System numbers for clarification.

(2) Individual PQRS Measures Available for Reporting for 2014 and Beyond

In the CY 2014 PFS proposed rule, we proposed to include additional measures in the PQRS measure set for 2014 and beyond (see Table 52, 78 FR 43379). We solicited and received public comment on these proposed measures.

Table 52 provides the individual quality measures and measures included in the PQRS measures groups we are finalizing for 2014 and beyond. The comments received and our responses to these comments are also contained in Table 52. Please note that Table 52 also provides certain measures we previously finalized for 2013 or 2014 and beyond in the CY 2013 PFS final rule with comment period (*see* Table 95, 77 FR 69215). Please also note that, in the CY 2014 proposed rule, in an effort t to move away from claims-based process measures, we proposed to change the reporting mechanisms for which certain measures were previously reportable (78 FR 43474). Please note that the comments we received on these proposed reporting mechanism changes, as well as our responses are also specified in Table 52.

Furthermore, CMS recognizes that updated clinical guidelines for cholesterol screening were recently released. The measures related to cholesterol screening contained in Table 52 do not reflect these recently updated guidelines. CMS will work to address any potential changes related to these new guidelines in future rulemaking

TABLE 52: Final Individual Quality Measures and Those Included in Measures Groups for the Physician Quality Reporting System to be Available for Satisfactory Reporting via Claims, Registry, or EHR Beginning in 2014

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
0059/	122v2	Effective Clinical Care	Diabetes: Hemoglobin A1c Poor Control: Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period. This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).	NCQA	X	X	X	X	X	MU2 ACO
0064/	163v2	Effective Clinical Care	Diabetes: Low Density Lipoprotein (LDL) Management: Percentage of patients 18–75 years of age with diabetes whose LDL-C was adequately controlled (<100 mg/dL) during the measurement period. This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).	NCQA	X	X	X		X	MU2 Million Hearts
0081/	135v2	Effective Clinical Care	Heart Failure (HF): Angiotensin- Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker	AMA- PCPI/ACCF/AHA		X	X		X	MU2

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures	Other Quality	Reporting Programs
			(ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD): Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB therapy either within a 12 month period when seen in the outpatient setting OR at each hospital discharge This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).								
0067/		Effective Clinical Care	Coronary Artery Disease (CAD): Antiplatelet Therapy: Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who were prescribed aspirin or clopidogrel *The EHR-based reporting mechanism is no longer available for reporting this measure for 2014 and beyond.*	AMA- PCPI/ACCF/AHA	X	X			X		

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures	Other Quality	Reporting Programs
			We solicited but received no public comment on this proposed measure. In an effort to align with the EHR Incentive Program, this measure will no longer be reportable via EHR beginning in 2014. The alignment of measures contained within multiple CMS reporting programs eases the burden of reporting and encourages eligible professionals to submit quality clinical data on care provided for Medicare beneficiaries. Alignment also promotes a robust data source and consistency in analysis, which supports other quality programs within CMS. For the reasons previously stated, we are finalizing the removal of the EHR-based option beginning in 2014.								
0070/	145v2	Effective Clinical Care	Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF < 40%): Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease	AMA- PCPI/ ACCF/AHA		X	X			M	U2

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
			seen within a 12 month period who also have prior MI OR a current or LVEF < 40% who were prescribed beta-blocker therapy							
			This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).							
0083/	144v2	Effective Clinical Care	Heart Failure (HF): Beta-Blocker	AMA- PCPI/		X	X	X	X	MU2
8			Therapy for Left Ventricular Systolic Dysfunction (LVSD): Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed beta-blocker therapy either within a 12 month period when seen in the outpatient setting OR at each hospital discharge This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).	ACCF/AHA						ACO
0105/	128v2	Effective Clinical Care	Anti-depressant Medication Management: Percentage of patients 18	NCQA		X	X			MU2

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures	Other Onality	Reporting	Programs
9			years of age and older who were diagnosed with major depression and treated with antidepressant medication, and who remained on antidepressant medication treatment. Two rates are reported a. Percentage of patients who remained on an antidepressant medication for at least 84 days (12 weeks). b. Percentage of patients who remained on an antidepressant medication for at least 180 days (6 months). *The claims-based reporting option is no longer available for reporting this measure for 2014 and beyond, additionally, the EHR-based reporting option is available for reporting this measure beginning in 2014.* Several commenters were concerned with CMS' proposal to eliminate the claims-based reporting option for this measure, stating eligible professionals who may have reported this measure will no longer be able to participate in PQRS. CMS appreciates the commenters' concerns but notes that this measure will still be available for registry-based reporting, along with									

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality	Reporting Programs
			additional clinically-related measures. Eligible professionals who report this measure will still have an opportunity to participate in PQRS using the registry-based reporting option. As stated in the proposed rule, 2012 claims data indicates a low threshold of eligible professionals reporting this measure via claims. CMS intends to streamline the reporting options available under the PQRS and to eliminate reporting options that are not widely used. Additionally, in an effort to align with the EHR Incentive Program, this measure will be reportable via EHR beginning in 2014. The alignment of measures contained within multiple CMS reporting programs eases the burden of reporting and encourages eligible professionals to submit quality clinical data on care provided for Medicare beneficiaries. Alignment also promotes a robust data source and consistency in analysis, which supports other quality programs within CMS. For the reasons previously stated, we are finalizing the removal of the claims-based option and the addition of the EHR-based reporting option for this measure beginning in 2014.								
0086/	143v2	Effective Clinical Care	Primary Open-Angle Glaucoma	AMA- PCPI/	X	X	X			MU	U <mark>2</mark>

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality	Reporting Programs
12			(POAG): Optic Nerve Evaluation: Percentage of patients aged 18 years and older with a diagnosis of primary open-angle glaucoma (POAG) who have an optic nerve head evaluation during one or more office visits within 12 months This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR	NCQA							
0087/		Effective Clinical Care	Age-Related Macular Degeneration (AMD): Dilated Macular Examination: Percentage of patients aged 50 years and older with a diagnosis of age-related macular degeneration (AMD) who had a dilated macular examination performed which included documentation of the presence or absence of macular thickening or hemorrhage AND the level of macular degeneration severity during one or more office visits within 12 months This measure was finalized for	AMA- PCPI/ NCQA	X	X					

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
			inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).							
0088/	167v2	Effective Clinical Care	Diabetic Retinopathy: Documentation of Presence or Absence of Macular Edema and Level of Severity of Retinopathy: Percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed which included documentation of the level of severity of retinopathy and the presence or absence of macular edema during one or more office visits within 12 months This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).	AMA- PCPI/ NCQA	X	X	X			MU2
0089/	142v2	Effective Clinical Care	Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care: Percentage of patients aged 18 years and older with a diagnosis of diabetic	AMA- PCPI/ NCQA	X	X	X			MU2

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures	Groups	Other Quality	Keporting Programs
			retinopathy who had a dilated macular or fundus exam performed with									
			documented communication to the									
			physician who manages the ongoing									
			care of the patient with diabetes									
			mellitus regarding the findings of the									
			macular or fundus exam at least once									
			within 12 months									
			This measure was finalized for									
			inclusion in 2014 PQRS in the CY 2013									
			PFS Final Rule (see Table 95 at 77 FR									
			69215).									
			However, please note that we are									
			updating the domain for this measure									
			from the Communication Care									
			Coordination domain. We are making									
			this change to align with the domains									
			indicated in the EHR Incentive Program									
			final rule for 2014. It is necessary for the domains for EHR measures within									
			the EHR Incentive Program and the									
			PQRS to create consistency for the									
			EHR systems used to report these									
			measures have one set of logic.									

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality	Reporting Programs
0270/20		Patient Safety	Perioperative Care: Timing of Prophylactic Parenteral Antibiotic – Ordering Physician: Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for prophylactic parenteral antibiotics, who have an order for prophylactic parenteral antibiotic to be given within one hour (if fluoroquinolone or vancomycin, two hours), prior to the surgical incision (or start of procedure when no incision is required) This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).	AMA- PCPI/ NCQA	X	X			X		
0268/		Patient Safety	Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second Generation Cephalosporin: Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second generation cephalosporin prophylactic antibiotic, who had an	AMA- PCPI/ NCQA	X	X			X		

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality	Keporting Programs
			order for a first OR second generation cephalosporin for antimicrobial prophylaxis								
			This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).								
0271/22		Patient Safety	Perioperative Care: Discontinuation of Prophylactic Parenteral Antibiotics (Non-Cardiac Procedures): Percentage of non-cardiac surgical patients aged 18 years and older undergoing procedures with the indications for prophylactic parenteral antibiotics AND who received a prophylactic parenteral antibiotic, who have an order for discontinuation of prophylactic parenteral antibiotics within 24 hours of surgical end time This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).	AMA- PCPI/ NCQA	X	X			X		

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web	Measures	Groups	Other Quality	Reporting Programs
0239/23		Patient Safety	Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients): Percentage of surgical patients aged 18 years and older undergoing procedures for which VTE prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low-Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).	AMA- PCPI/ NCQA	X	X			X			
0045/24		Communication and Care Coordination	Osteoporosis: Communication with the Physician Managing On-going Care Post-Fracture of Hip, Spine or Distal Radius for Men and Women Aged 50 Years and Older: Percentage of patients aged 50 years and older treated for a hip, spine or distal radial	AMA- PCPI/ NCQA	X	X						

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality	Reporting Programs	Frograms
			fracture with documentation of communication with the physician managing the patient's on-going care that a fracture occurred and that the patient was or should be tested or treated for osteoporosis This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR									
0092/		Effective Clinical Care	69215). Aspirin at Arrival for Acute	AMA- PCPI/	X	X						_
28			Myocardial Infarction (AMI): Percentage of patients, regardless of age, with an emergency department discharge diagnosis of acute myocardial infarction (AMI) who had documentation of receiving aspirin within 24 hours before emergency department arrival or during emergency department stay This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).	NCQA								

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure	Claims	Registry	EHR	GPRO (Web	Measures	Groups	Other Quality	Reporting Programs
0269/		Patient Safety	Perioperative Care: Timing of	AMA- PCPI/	X	X						
30			Prophylactic Antiobiotic—	NCQA								ļ
			Administering Physician: Percentage									ļ
			of surgical patients aged 18 years and									ļ
			older who receive an anesthetic when									ļ
			undergoing procedures with the									ļ
			indications for prophylactic parenteral									ļ
			antibiotics for whom administration of									ļ
			a prophylactic parenteral antibiotic									ļ
			ordered has been initiated within one									ļ
			hour (if fluoroquinolone or									ļ
			vancomycin, two hours) prior to the									ļ
			surgical incision (or start of procedure									ļ
			when no incision is required)									
			This measure was finalized for									
			inclusion in 2014 PQRS in the CY 2013									ļ
			PFS Final Rule (see Table 95 at 77 FR									ļ
			69215).									
0240/		Effective Clinical Care	Stroke and Stroke Rehabilitation:	AMA- PCPI/	X	X						
31			Venous Thromboembolism (VTE)	NCQA								ļ
			Prophylaxis for Ischemic Stroke or									ļ
			Intracranial Hemorrhage: Percentage									
			of patients aged 18 years and older with									
			a diagnosis of ischemic stroke or									
			intracranial hemorrhage who were									

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality	Reporting Programs
			administered venous thromboembolism								
			(VTE) prophylaxis the day of or the day								
			after hospital admission								
			This measure was finalized for								
			inclusion in 2014 PQRS in the CY 2013								
			PFS Final Rule (see Table 95 at 77 FR								
			69215).								
0325/		Effective Clinical Care	Stroke and Stroke Rehabilitation:	AMA- PCPI/	X	X					
32			Discharged on Antithrombotic	NCQA							
			Therapy: Percentage of patients aged								
			18 years and older with a diagnosis of								
			ischemic stroke or transient ischemic								
			attack (TIA) who were prescribed								
			antithrombotic therapy at discharge								
			This measure was finalized for								
			inclusion in 2014 PQRS in the CY 2013								
			PFS Final Rule (see Table 95 at 77 FR								
			69215).								
0241/		Effective Clinical Care	Stroke and Stroke Rehabilitation:	AMA- PCPI/		X					
33			Anticoagulant Therapy Prescribed	NCQA							
			for Atrial Fibrillation (AF) at								
			Discharge: Percentage of patients aged								
			18 years and older with a diagnosis of								
			ischemic stroke or transient ischemic								

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality	Reporting Programs
			attack (TIA) with documented permanent, persistent, or paroxysmal atrial fibrillation who were prescribed an anticoagulant at discharge This measure was finalized for inclusion in 2014 PQRS in the CY 2013								
			PFS Final Rule (see Table 95 at 77 FR 69215).								
0243/35		Effective Clinical Care	Stroke and Stroke Rehabilitation: Screening for Dysphagia: Percentage of patients aged 18 years and older with a diagnosis of ischemic stroke or intracranial hemorrhage who receive any food, fluids or medication by mouth (PO) for whom a dysphagia screening was performed prior to PO intake in accordance with a dysphagia screening tool approved by the institution in which the patient is receiving care This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).	AMA- PCPI/ NCQA	X	X					

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web	Measures	Other Quality	Reporting	Programs
0244/36		Effective Clinical Care	Stroke and Stroke Rehabilitation: Rehabilitation Services Ordered: Percentage of patients aged 18 years and older with a diagnosis of ischemic stroke or intracranial hemorrhage for whom occupational, physical, or speech rehabilitation services were ordered at or prior to inpatient discharge OR documentation that no rehabilitation services are indicated at or prior to inpatient discharge This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).	AMA- PCPI/ NCQA	X	X						
0046/39		Effective Clinical Care	Screening or Therapy for Osteoporosis for Women Aged 65 Years and Older: Percentage of female patients aged 65 years and older who have a central dual-energy X- ray absorptiometry (DXA) measurement ordered or performed at least once since age 60 or pharmacologic therapy prescribed within 12 months	AMA- PCPI/ NCQA	X	X			X			

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures	Other Quality	Reporting Programs
			*The EHR-based reporting mechanism								
			is no longer available for reporting this								
			measure for 2014 and beyond.*								
			In an effort to align with the EHR								
			Incentive Program, this measure will no								
			longer be reportable via EHR beginning								
			in 2014. The alignment of measures								
			contained within multiple CMS								
			reporting programs eases the burden of								
			reporting and encourages eligible								
			professionals to submit quality clinical								
			data on care provided for Medicare								
			beneficiaries. Alignment also promotes a robust data source and consistency in								
			analysis, which supports other quality								
			programs within CMS. For the reasons								
			previously stated, we are finalizing the								
			removal of the EHR-based option								
			beginning in 2014.								
0048/		Effective Clinical Care	Osteoporosis: Management	AMA- PCPI/	X	X					
40			Following Fracture of Hip, Spine or	NCQA							
			Distal Radius for Men and Women								
			Aged 50 Years and Older: Percentage								
			of patients aged 50 years and older								
			with fracture of the hip, spine, or distal								

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality	Reporting Programs
			radius who had a central dual-energy X-ray absorptiometry (DXA) measurement ordered or performed or pharmacologic therapy prescribed								
			This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).								
0049/		Effective Clinical Care	Osteoporosis: Pharmacologic Therapy for Men and Women Aged 50 Years and Older: Percentage of patients aged 50 years and older with a diagnosis of osteoporosis who were prescribed pharmacologic therapy within 12 months This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).	AMA- PCPI/ NCQA	X	X					
0134/43		Effective Clinical Care	Coronary Artery Bypass Graft (CABG): Use of Internal Mammary Artery (IMA) in Patients with Isolated CABG Surgery: Percentage of patients aged 18 years and older	STS	X	X			X		

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality	Keporting Programs
			undergoing isolated CABG surgery who received an IMA graft This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).								
0236/		Effective Clinical Care	Coronary Artery Bypass Graft (CABG): Preoperative Beta-Blocker in Patients with Isolated CABG Surgery: Percentage of isolated Coronary Artery Bypass Graft (CABG) surgeries for patients aged 18 years and older who received a beta-blocker within 24 hours prior to surgical incision This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR	CMS	X	X			X		
0637/		Patient Safety	69215). Perioperative Care: Discontinuation of Prophylactic Parenteral Antibiotics (Cardiac Procedures): Percentage of cardiac surgical patients aged 18 years and older undergoing	AMA- PCPI/ NCQA	X	X					

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality	Reporting Programs
			procedures with the indications for prophylactic parenteral antibiotics AND who received a prophylactic parenteral antibiotic, who have an order for discontinuation of prophylactic parenteral antibiotics within 48 hours of surgical end time This measure was finalized for								
			inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).								
0097/46		Patient Safety	Medication Reconciliation: Percentage of patients aged 65 years and older discharged from any inpatient facility (e.g., hospital, skilled nursing facility, or rehabilitation facility) and seen within 30 days following discharge in the office by the physician, prescribing practitioner, registered nurse, or clinical pharmacist providing on-going care who had a reconciliation of the discharge medications with the current medication list in the outpatient medical record	AMA- PCPI/ NCQA	X	X		X		ACC	XO

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures	Other Quality	Reporting	Programs
			documented This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).									
0326/47		Communication and Care Coordination	Advance Care Plan: Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan *The EHR-based reporting mechanism is no longer available for reporting this measure for 2014 and beyond.* We solicited but received no public comment on this measure. In an effort to align with the EHR Incentive Program, this measure will no longer be reportable via EHR beginning in 2014.	AMA- PCPI/ NCQA	X	X						

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality	Reporting Programs
			The alignment of measures contained within multiple CMS reporting programs eases the burden of reporting and encourages eligible professionals to submit quality clinical data on care provided for Medicare beneficiaries. Alignment also promotes a robust data source and consistency in analysis, which supports other quality programs within CMS. For the reasons previously stated, we are finalizing the removal of the EHR-based option beginning in 2014.								
0098/ 48		Effective Clinical Care	Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older: Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months *The EHR-based reporting mechanism is no longer available for reporting this measure for 2014 and beyond.*	AMA- PCPI/ NCQA	X	X			X		

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures	Other Quality	Reporting Programs
			In an effort to align with the EHR Incentive Program, this measure will no longer be reportable via EHR beginning in 2014. The alignment of measures contained within multiple CMS reporting programs eases the burden of reporting and encourages eligible professionals to submit quality clinical data on care provided for Medicare beneficiaries. Alignment also promotes a robust data source and consistency in analysis, which supports other quality programs within CMS. For the reasons previously stated, we are finalizing the removal of the EHR-based option beginning in 2014.								
0099/		Effective Clinical Care	Urinary Incontinence:	AMA- PCPI/	X	X					
49			Characterization of Urinary Incontinence in Women Aged 65	NCQA							
			Years and Older: Percentage of								ļ
			female patients aged 65 years and older								
			with a diagnosis of urinary incontinence								
			whose urinary incontinence was								ļ
			characterized at least once within 12								

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures	Other Quality	Reporting Programs
			months This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).								
0100/		Person and Caregiver- Centered Experience and Outcomes	Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older: Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).	AMA- PCPI/ NCQA	X	X					
0091/		Effective Clinical Care	Chronic Obstructive Pulmonary Disease (COPD): Spirometry Evaluation: Percentage of patients aged 18 years and older with a diagnosis of COPD who had spirometry evaluation results documented	AMA-PCPI	X	X			X		

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting	Programs
			This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).								
0102/ 52		Effective Clinical Care	Chronic Obstructive Pulmonary Disease (COPD): Inhaled Bronchodilator Therapy: Percentage of patients aged 18 years and older with a diagnosis of COPD and who have an FEV ₁ /FVC less than 60% and have symptoms who were prescribed an inhaled bronchodilator This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).	AMA-PCPI	X	X			X		
0047/		Effective Clinical Care	Asthma: Pharmacologic Therapy for Persistent Asthma - Ambulatory Care Setting: Percentage of patients aged 5 through 64 years with a diagnosis of persistent asthma who were prescribed long-term control medication *The claims-based reporting option is	AMA- PCPI/ NCQA		X			X		

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure	Claims	Registry	EHR	GPRO (Web Interface)*	Measures	Other Quality	Reporting Programs	
			no longer available for reporting this									
			measure for 2014 and beyond.*									
			We solicited but received no public									
			comment on removing the claims-based									
			reporting mechanism as an option to									
			report this measure. 2012 claims data									
			indicates a low threshold of eligible									
			professionals reporting this measure via									
			claims. CMS intends to streamline the									
			reporting options available under the									
			PQRS and to eliminate reporting									
			options that are not widely used. For									
			these reasons, we are finalizing the removal of the claims-based option for									
			this measure beginning in 2014.									
0090/		Effective Clinical Care	Emergency Medicine: 12-Lead	AMA- PCPI/	X	X				+		-
54		Effective Chinical Cure	Electrocardiogram (ECG) Performed	NCQA	21	21						
			for Non-Traumatic Chest Pain:	110 211								
			Percentage of patients aged 40 years									
			and older with an emergency									
			department discharge diagnosis of non-									
			traumatic chest pain who had a 12-lead									
			electrocardiogram (ECG) performed									
			This measure was finalized for									

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web	Measures	Groups	Other Quality	Reporting Programs
			inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).									
0093/		Effective Clinical Care	Emergency Medicine: 12-Lead Electrocardiogram (ECG) Performed for Syncope: Percentage of patients aged 60 years and older with an emergency department discharge diagnosis of syncope who had a 12-lead electrocardiogram (ECG) performed This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).	AMA- PCPI/ NCQA	X	X						
0232/ 56		Effective Clinical Care	Emergency Medicine: Community-Acquired Bacterial Pneumonia (CAP): Vital Signs: Percentage of patients aged 18 years and older with a diagnosis of community-acquired bacterial pneumonia (CAP) with vital signs documented and reviewed This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR	AMA- PCPI/ NCQA	X	X						

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures	Other Quality	Reporting	Programs
			69215).									
0096/		Effective Clinical Care	Emergency Medicine: Community-	AMA- PCPI/	X	X						
59			Acquired Bacterial Pneumonia	NCQA								
			(CAP): Empiric Antibiotic:									
			Percentage of patients aged 18 years									
			and older with a diagnosis of									
			community-acquired bacterial									
			pneumonia (CAP) with an appropriate									
			empiric antibiotic prescribed									
			This measure was finalized for									
			inclusion in 2014 PQRS in the CY 2013									
			PFS Final Rule (see Table 95 at 77 FR									
			69215).									
0001/		Effective Clinical Care	Asthma: Assessment of Asthma	AMA- PCPI/		X			X			
64			Control – Ambulatory Care Setting:	NCQA								
			Percentage of patients aged 5 through									
			64 years with a diagnosis of asthma									
			who were evaluated at least once during									
			the measurement period for asthma									
			control (comprising asthma impairment									
			and asthma risk)									
			*The claims-based and EHR-based									
			reporting options are no longer									
			available for reporting this measure for									

NQF/ PQRS CMS E-Measure	Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web	Measures	Groups	Other Quality	Keporting Programs
		2014 and beyond*									
		We solicited but received no public comment on this measure, including not having this measure reportable via the claims and EHR-based reporting mechanisms beginning ni 2014. 2012 claims data indicates a low threshold of eligible professionals reporting this measure via claims. CMS intends to streamline the reporting options available under the PQRS and to eliminate reporting options that are not widely used. Additionally, in an effort to align with the EHR Incentive Program, this measure will no longer be reportable via EHR beginning in 2014. The alignment of measures contained within multiple CMS reporting programs eases the burden of reporting and encourages eligible professionals to submit quality clinical data on care provided for Medicare beneficiaries. Alignment also promotes a robust data source and consistency in analysis, which supports other quality programs									

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality	Keporting Programs
			within CMS. For these reasons, we are								
			finalizing the removal of this measure								
			from the claims-based and EHR-based								
			reporting options beginning in 2014.								
0069/	154v2	Efficiency and Cost	Appropriate Treatment for Children	NCQA		X	X			MU	J2
65		Reduction	with Upper Respiratory Infection								
			(URI): Percentage of children 3								
			months-18 years of age who were								
			diagnosed with upper respiratory								
			infection (URI) and were not dispensed								
			an antibiotic prescription on or three								
			days after the episode.								
			*The claims-based reporting option is								
			no longer available for reporting this								
			measure for 2014 and beyond,								
			additionally, the EHR-based reporting								
			option is available for reporting this								
			measure beginning in 2014.*								
			We solicited but received no public								
			comment on this measure. 2012 claims								
			data indicates a low threshold of								
			eligible professionals reporting this								
			measure via claims. CMS intends to								
			streamline the reporting options								

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality	Reporting Programs
			available under the PQRS and to								
			eliminate reporting options that are not								
			widely used. Additionally, in an effort								
			to align with the EHR Incentive								
			Program, this measure will be								
			reportable via EHR beginning in 2014.								
			The alignment of measures contained								
			within multiple CMS reporting								
			programs eases the burden of reporting								
			and encourages eligible professionals to								
			submit quality clinical data on care								
			provided for Medicare beneficiaries.								
			Alignment also promotes a robust data								
			source and consistency in analysis,								
			which supports other quality programs								
			within CMS. For the reasons previously								
			stated, we are finalizing the removal of								
			the claims-based option and the								
			addition of the EHR-based reporting								
			option for this measure beginning in								
			2014.								
0002/	146v2	Efficiency and Cost	Appropriate Testing for Children	NCQA		X	X			M	U2
66		Reduction	with Pharyngitis: Percentage of								
			children 2-18 years of age who were								
			diagnosed with pharyngitis, ordered an								
			antibiotic and received a group A								

Groups Other Quality Reporting Programs	Measures Groups	GFRO (web Interface)*	EHR	Registry	Claims	Measure Steward	Measure Title and Description [¥]	National Quality Strategy Domain	CMS E-Measure	NQF/ PQRS
							streptococcus (strep) test for the episode.			
							The claims-based reporting option is no longer available for reporting this measure for 2014 and beyond.			
							We solicited but received no public comment on this measure. 2012 claims data indicates a low threshold of			
							eligible professionals reporting this measure via claims. CMS intends to			
							streamline the reporting options available under the PQRS and to eliminate reporting options that are not			
							finalizing the removal of the claims- based option for this measure beginning			
				X	X	AMA- PCPI/		Effective Clinical Care		0377/
		ļ				ASH	Syndrome (MDS) and Acute			67
		ļ					Leukemias: Baseline			
		ļ					Cytogenetic Testing Performed on			
		ļ								
				X	X		available under the PQRS and to eliminate reporting options that are not widely used. For these reasons, we are finalizing the removal of the claims-based option for this measure beginning in 2014. Hematology: Myelodysplastic Syndrome (MDS) and Acute Leukemias: Baseline	Effective Clinical Care		

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting	Programs
			(MDS) or an acute leukemia who had baseline cytogenetic testing performed on bone marrow								
			This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).								
0378/ 68		Effective Clinical Care	Hematology: Myelodysplastic	AMA- PCPI/ ASH	X	X					
			Syndrome (MDS): Documentation of Iron Stores in Patients Receiving Erythropoietin Therapy: Percentage of patients aged 18 years and older with a diagnosis of myelodysplastic syndrome (MDS) who are receiving erythropoietin therapy with documentation of iron stores within 60 days prior to initiating erythropoietin therapy This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).	ASII							
0380/		Effective Clinical Care	Hematology: Multiple Myeloma:	AMA- PCPI/	X	X					
69			Treatment with Bisphosphonates:	ASH							

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
			Percentage of patients aged 18 years and older with a diagnosis of multiple myeloma, not in remission, who were prescribed or received intravenous bisphosphonate therapy within the 12-month reporting period This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).							
0379/70		Effective Clinical Care	Hematology: Chronic Lymphocytic Leukemia (CLL): Baseline Flow Cytometry: Percentage of patients aged 18 years and older seen within a 12 month reporting period with a diagnosis of chronic lymphocytic leukemia (CLL) made at any time during or prior to the reporting period who had baseline flow cytometry studies performed and documented in the chart This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).	AMA- PCPI/ ASH	X	X				
0387/	140v1	Effective Clinical Care	Breast Cancer: Hormonal Therapy for Stage IC-IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer: Percentage of female patients aged 18	AMA-PCPI/ ASCO/ NCCN	X	X	X		X	MU2

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality	Reporting Programs
			years and older with Stage IC through IIIC, ER or PR positive breast cancer who were prescribed tamoxifen or aromatase inhibitor (AI) during the 12-month reporting period This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).								
0385/72	141v3	Effective Clinical Care	Colon Cancer: Chemotherapy for AJCC Stage III Colon Cancer Patients: Percentage of patients aged 18 through 80 years with AJCC Stage III colon cancer who are referred for adjuvant chemotherapy, prescribed adjuvant chemotherapy, or have previously received adjuvant chemotherapy within the 12-month reporting period. This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).	AMA-PCPI/ ASCO/NCCN	X	X	X		X	MU	J2
0464/		Patient Safety	Prevention of Catheter-Related	AMA-PCPI	X	X					

CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web	Measures	Groups	Other Quality	Reporting Programs
		Bloodstream Infections (CRBSI):									
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		1 - 1									
		, ,									
		•									
		current guideline)] followed									
		This measure was finalized for									
		`									
		1	AMA-PCPI		X						
	Care Coordination										
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	CMS E-Measure	National Quality Strategy Domain Communication and Care Coordination	Bloodstream Infections (CRBSI): Central Venous Catheter (CVC) Insertion Protocol: Percentage of patients, regardless of age, who undergo CVC insertion for whom CVC was inserted with all elements of maximal sterile barrier technique [cap AND mask AND sterile gown AND sterile gloves AND a large sterile sheet AND hand hygiene AND 2% chlorhexidine for cutaneous antisepsis (or acceptable alternative antiseptics per current guideline)] followed This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215). Communication and Adult Kidney Disease: Hemodialysis	Bloodstream Infections (CRBSI): Central Venous Catheter (CVC) Insertion Protocol: Percentage of patients, regardless of age, who undergo CVC insertion for whom CVC was inserted with all elements of maximal sterile barrier technique [cap AND mask AND sterile gown AND sterile gloves AND a large sterile sheet AND hand hygiene AND 2% chlorhexidine for cutaneous antisepsis (or acceptable alternative antiseptics per current guideline)] followed This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215). Communication and Care Coordination Adult Kidney Disease: Hemodialysis Adequacy: Solute: Percentage of calendar months within a 12-month period during which patients aged 18 years and older with a diagnosis of End Stage Renal Disease (ESRD) receiving hemodialysis three times a week for ≥	Bloodstream Infections (CRBSI): Central Venous Catheter (CVC) Insertion Protocol: Percentage of patients, regardless of age, who undergo CVC insertion for whom CVC was inserted with all elements of maximal sterile barrier technique [cap AND mask AND sterile gown AND sterile gloves AND a large sterile sheet AND hand hygiene AND 2% chlorhexidine for cutaneous antisepsis (or acceptable alternative antiseptics per current guideline)] followed This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215). 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Communication and Care Coordination Adult Kidney Disease: Hemodialysis Adequacy: Solute: Percentage of calendar months within a 12-month period during which patients aged 18 years and older with a diagnosis of End Stage Renal Disease (ESRD) receiving hemodialysis three times a week for ≥	Bloodstream Infections (CRBSI): Central Venous Catheter (CVC) Insertion Protocol: Percentage of patients, regardless of age, who undergo CVC insertion for whom CVC was inserted with all elements of maximal sterile barrier technique [cap AND mask AND sterile gown AND sterile gloves AND a large sterile sheet AND hand hygiene AND 2% chlorhexidine for cutaneous antisepsis (or acceptable alternative antiseptics per current guideline)] followed This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215). Communication and Care Coordination Adult Kidney Disease: Hemodialysis Adequacy: Solute: Percentage of calendar months within a 12-month period during which patients aged 18 years and older with a diagnosis of End Stage Renal Disease (ESRD) receiving hemodialysis three times a week for ≥	Bloodstream Infections (CRBSI): Central Venous Catheter (CVC) Insertion Protocol: Percentage of patients, regardless of age, who undergo CVC insertion for whom CVC was inserted with all elements of maximal sterile barrier technique [cap AND mask AND sterile gown AND sterile gloves AND a large sterile sheet AND hand hygien AND 2% chlorhexidine for cutaneous antisepsis (or acceptable alternative antiseptics per current guideline)] followed This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215). Communication and Care Coordination Adult Kidney Disease: Hemodialysis Adequacy: Solute: Percentage of calendar months within a 12-month period during which patients aged 18 years and older with a diagnosis of End Stage Renal Disease (ESRD) receiving hemodialysis three times a week for ≥	Bloodstream Infections (CRBSI): Central Venous Catheter (CVC) Insertion Protocol: Percentage of patients, regardless of age, who undergo CVC insertion for whom CVC was inserted with all elements of maximal sterile barrier technique [cap AND mask AND sterile gown AND sterile gloves AND a large sterile sheet AND hand hygiene AND 2% chlorhexidine for cutaneous antisepsis (or acceptable alternative antiseptics per current guideline)] followed This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215). Communication and Care Coordination Adult Kidney Disease: Hemodialysis Adequacy: Solute: Percentage of calendar months within a 12-month period during which patients aged 18 years and older with a diagnosis of End Stage Renal Disease (ESRD) receiving hemodialysis three times a week for ≥

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures	Other Onality	Reporting	Programs
			This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).									
0321/82		Communication and Care Coordination	Adult Kidney Disease: Peritoneal Dialysis Adequacy: Solute: Percentage of patients aged 18 years and older with a diagnosis of End Stage Renal Disease (ESRD) receiving peritoneal dialysis who have a total Kt/V ≥ 1.7 per week measured once every 4 months This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).	AMA-PCPI		X						
0393/83		Effective Clinical Care	Hepatitis C: Confirmation of Hepatitis C Viremia: Percentage of patients aged 18 years and older who are hepatitis C antibody positive seen for an initial evaluation for whom hepatitis C virus (HCV) RNA testing was ordered or previously performed This measure was finalized for	AMA-PCPI		X						

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting	Programs
			inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).								
0395/84		Effective Clinical Care	Hepatitis C: Ribonucleic Acid (RNA) Testing Before Initiating Treatment: Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C who started antiviral treatment within the 12 month reporting period for whom hepatitis C virus (HCV) genotype testing was performed within 12 months prior to initiation of antiviral treatment *The claims-based reporting option is no longer available for reporting this measure for 2014 and beyond.* We solicited but received no public comment on this measure. CMS would like to note that although this measure was not listed in our proposal as having a reporting option change, we are finalizing it as registry-only beginning in 2014. CMS believes it necessary to maintain consistency of clinically-	AMA-PCPI		X			X		

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web	Interface)" Measures	Groups	Other Quality	Reporting Programs
			related measures available within a particular reporting option; therefore, we are eliminating this measure from the claims-based reporting option. 2012 claims data indicates a low threshold of eligible professionals reporting this measure via claims. CMS intends to streamline the reporting options available under the PQRS and to eliminate reporting options that are not widely used. Eligible professionals who report this measure will still have an opportunity to participate in PQRS using the registry-based reporting option. For these reasons, we are finalizing the removal of the claims-based option for									
0396/		Effective Clinical Care	this measure beginning in 2014. Hepatitis C: HCV Genotype Testing Prior to Treatment: Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C who started antiviral treatment within the 12 month reporting period for whom quantitative hepatitis C virus (HCV)	AMA-PCPI		X			X	ζ		

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web	Measures	Groups	Other Quality	Reporting Programs
			RNA testing was performed within 12									
			months prior to initiation of antiviral									
			treatment									
			*The claims-based reporting option is									
			no longer available for reporting this									
			measure for 2014 and beyond.*									
			We solicited but received no public									
			comment on this measure. CMS would									
			like to note that although this measure									
			was not listed in our proposal as having									
			a reporting option change, we are									
			finalizing it as registry-only beginning in 2014. CMS believes it necessary to									
			maintain consistency of clinically-									
			related measures available within a									
			particular reporting option; therefore,									
			we are eliminating this measure from									
			the claims-based reporting option. 2012									
			claims data indicates a low threshold of									
			eligible professionals reporting this									
			measure via claims. CMS intends to									
			streamline the reporting options									
			available under the PQRS and to									
			eliminate reporting options that are not									

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality	Reporting Programs
			widely used. Eligible professionals who report this measure will still have an opportunity to participate in PQRS using the registry-based reporting option. For these reasons, we are finalizing the removal of the claims-based option for this measure beginning in 2014.								
0398/87		Effective Clinical Care	Hepatitis C: Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) Testing Between 4-12 Weeks After Initiation of Treatment: Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C who are receiving antiviral treatment for whom quantitative hepatitis C virus (HCV) RNA testing was performed between 4- 12 weeks after the initiation of antiviral treatment *The claims-based reporting option is no longer available for reporting this measure for 2014 and beyond.* We solicited but received no public	AMA-PCPI		X			X		

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality	Reporting Programs
			comment on this measure. 2012 claims data indicates a low threshold of eligible professionals reporting this measure via claims. CMS intends to streamline the reporting options available under the PQRS and to eliminate reporting options that are not widely used. For these reasons, we are finalizing the removal of the claims-based option for this measure beginning in 2014.								
0653/ 91		Effective Clinical Care	Acute Otitis Externa (AOE): Topical Therapy: Percentage of patients aged 2 years and older with a diagnosis of AOE who were prescribed topical preparations This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).	AMA-PCPI	X	X					
0654/ 93		Communication and Care Coordination	Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use: Percentage of patients aged 2 years and older with a	AMA-PCPI	X	X					

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Renorting	reporting Programs
			diagnosis of AOE who were <u>not</u> <u>prescribed</u> systemic antimicrobial therapy								
			This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).								
0391/99		Effective Clinical Care	Breast Cancer Resection Pathology Reporting: pT Category (Primary Tumor) and pN Category (Regional Lymph Nodes) with Histologic Grade: Percentage of breast cancer resection pathology reports that include the pT category (primary tumor), the pN category (regional lymph nodes), and the histologic grade This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).	AMA- PCPI/ CAP	X	X					
0392/ 100		Effective Clinical Care	Colorectal Cancer Resection Pathology Reporting: pT Category (Primary Tumor) and pN Category (Regional Lymph Nodes) with	AMA- PCPI/ CAP	X	X					

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure	Claims	Registry	EHR	GPRO (Web Interface)*	Measures	Other Quality	Reporting Programs
			Histologic Grade: Percentage of colon and rectum cancer resection pathology reports that include the pT category (primary tumor), the pN category (regional lymph nodes) and the histologic grade This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).								
0389/	129v3	Efficiency and Cost	Prostate Cancer: Avoidance of	AMA-PCPI	X	X	X			M	IU2
102		Reduction	Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients: Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy, OR cryotherapy who did not have a bone scan performed at any time since diagnosis of prostate cancer This measure was finalized for inclusion in 2014 PQRS in the CY 2013								

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures	Groups Other Onality	Reporting	Programs
			PFS Final Rule (see Table 95 at 77 FR 69215).									
0390/ 104		Effective Clinical Care	Prostate Cancer: Adjuvant Hormonal Therapy for High Risk Prostate Cancer Patients: Percentage of patients, regardless of age, with a diagnosis of prostate cancer at high risk of recurrence receiving external beam radiotherapy to the prostate who were prescribed adjuvant hormonal therapy (GnRH agonist or antagonist) This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).	AMA-PCPI	X	X						
0103/ 106		Effective Clinical Care	Adult Major Depressive Disorder (MDD): Comprehensive Depression Evaluation: Diagnosis and Severity: Percentage of patients aged 18 years and older with a new diagnosis or recurrent episode of major depressive disorder (MDD) with evidence that they met the Diagnostic and Statistical Manual of Mental Disorders (DSM)-IV-TR criteria for MDD AND for whom there is an assessment of depression severity during the visit in which a new diagnosis or recurrent episode was identified	AMA-PCPI	X	X						

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [*]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
			This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).							
0104/	161v2	Effective Clinical Care	Adult Major Depressive Disorder (MDD): Suicide Risk Assessment: Percentage of patients aged 18 years and older with a diagnosis of major depressive disorder (MDD) with a suicide risk assessment completed during the visit in which a new diagnosis or recurrent episode was identified *The EHR-based reporting option is available for reporting this measure beginning in 2014.* In an effort to align with the EHR Incentive Program, this measure will be reportable via EHR beginning in 2014. The alignment of measures contained within multiple CMS reporting programs eases the burden of reporting and encourages eligible professionals to submit quality clinical data on care provided for Medicare beneficiaries.	AMA-PCPI	X	X	X			MU2

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting	Programs
			Alignment also promotes a robust data source and consistency in analysis, which supports other quality programs								
			within CMS. For these reasons, we are finalizing the removal of the claims-								
			based option and the addition of the EHR-based reporting option for this measure beginning in 2014.								
0054/ 108		Effective Clinical Care	Rheumatoid Arthritis (RA): Disease Modifying Anti-Rheumatic Drug (DMARD) Therapy: Percentage of	NCQA	X	X			X		
			patients aged 18 years and older who were diagnosed with RA and were								
			prescribed, dispensed, or administered at least one ambulatory prescription for a DMARD								
			This measure was finalized for inclusion in 2014 PQRS in the CY 2013								
			PFS Final Rule (see Table 95 at 77 FR 69215).								
0050/		Person and Caregiver-	Osteoarthritis (OA): Function and	AMA-PCPI	X	X					
109		Centered Experience	Pain Assessment: Percentage of patient								
		and Outcomes	visits for patients aged 21 years and								
			older with a diagnosis of osteoarthritis (OA) with assessment for function and								

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
			pain This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).							
0041/	147v2	Community/ Population Health	Preventive Care and Screening: Influenza Immunization: Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).	AMA-PCPI	X	X	X	X	X	MU2 ACO
0043/	127v2	Effective Clinical Care	Pneumonia Vaccination Status for Older Adults: Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine. This measure was finalized for inclusion in 2014 PQRS in the CY 2013	NCQA	X	X	X	X	X	MU2 ACO

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
			PFS Final Rule (see Table 95 at 77 FR 69215).							
N/A/ 112	125v2	Effective Clinical Care	Breast Cancer Screening: Percentage of women 50 through 74 years of age who had a mammogram to screen for breast cancer within 27 months This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).	NCQA	X	X	X	X	X	MU2 ACO
0034/	130v2	Effective Clinical Care	Colorectal Cancer Screening: Percentage of patients 50-75 years of age who had appropriate screening for colorectal cancer. This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).	NCQA	X	X	X	X	X	MU2 ACO
0058/ 116		Efficiency and Cost Reduction	Antibiotic Treatment for Adults with Acute Bronchitis: Avoidance of Inappropriate Use: Percentage of adults 18 through 64 years of age with a diagnosis of acute bronchitis who were not prescribed or dispensed an	NCQA		X				

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures	Other Quality	Reporting Programs
			antibiotic prescription on or 3 days after the episode *The claims-based reporting option is no longer available for reporting this measure for 2014 and beyond.* 2012 claims data indicates a low threshold of eligible professionals reporting this measure via claims. CMS intends to streamline the reporting options available under the PQRS and to eliminate reporting options that are not widely used. For these reasons, we are finalizing the removal of the claims-based reporting option beginning in 2014.								
0055/	131v2	Effective Clinical Care	Diabetes: Eye Exam: Percentage of patients 18-75 years of age with diabetes who had a retinal or dilated eye exam by an eye care professional during the measurement period or a negative retinal eye exam (no evidence of retinopathy) in the 12 months prior to the measurement period This measure was finalized for inclusion in 2014 PQRS in the CY 2013	NCQA	X	X	X		X	M	U2

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
			PFS Final Rule (see Table 95 at 77 FR 69215).							
0066/		Effective Clinical Care	Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%): Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who also have diabetes OR a current or prior Left Ventricular Ejection Fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB therapy This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).	AMA- PCPI/ ACCF/AHA		X		X		ACO
0062/	134v2	Effective Clinical Care	Diabetes: Urine Protein Screening: The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period. This measure was finalized for inclusion in	NCQA	X	X	X		X	MU2

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality	Keporting Programs
			2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).								
1668/		Effective Clinical Care	Adult Kidney Disease: Laboratory Testing (Lipid Profile): Percentage of patients aged 18 years and older with a diagnosis of chronic kidney disease (CKD) (stage 3, 4, or 5, not receiving Renal Replacement Therapy [RRT]) who had a fasting lipid profile performed at least once within a 12-month period This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).	AMA-PCPI	X	X			X		
AQA adopted/ 122		Effective Clinical Care	Adult Kidney Disease: Blood Pressure Management: Percentage of patient visits for those patients aged 18 years and older with a diagnosis of chronic kidney disease (CKD) (stage 3, 4, or 5, not receiving Renal Replacement Therapy [RRT]) and proteinuria with a blood pressure < 130/80 mmHg OR ≥ 130/80 mmHg with a documented plan of care	AMA-PCPI	X	X			X		

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality	Reporting Programs
			This measure was finalized for								
			inclusion in 2014 PQRS in the CY 2013								
			PFS Final Rule (see Table 95 at 77 FR								
			69215).								
1666/		Effective Clinical Care	Adult Kidney Disease: Patients On	AMA-PCPI	X	X			X		
123			Erythropoiesis-Stimulating Agent								
			(ESA) - Hemoglobin Level > 12.0								
			g/dL: Percentage of calendar months								
			within a 12-month period during which								
			a hemoglobin level is measured for								
			patients aged 18 years and older with a								
			diagnosis of advanced chronic kidney								
			disease (CKD) (stage 4 or 5, not								
			receiving Renal Replacement Therapy								
			[RRT]) or End Stage Renal Disease								
			(ESRD) (who are on hemodialysis or								
			peritoneal dialysis) who are also								
			receiving erythropoiesis-stimulating								
			agent (ESA) therapy have a hemoglobin								
			level $> 12.0 \text{ g/dL}$								
			This measure was finalized for								
			inclusion in 2014 PQRS in the CY 2013								
			PFS Final Rule (see Table 95 at 77 FR								
			69215).								
0417/		Effective Clinical Care	Diabetes Mellitus: Diabetic Foot and	APMA		X					

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality	Reporting Programs	Livgiano
126			Ankle Care, Peripheral Neuropathy –							Ť		
			Neurological Evaluation: Percentage									
			of patients aged 18 years and older with									
			a diagnosis of diabetes mellitus who									
			had a neurological examination of their									
			lower extremities within 12 months									
			*The claims-based reporting option is									
			no longer available for reporting this									
			measure for 2014 and beyond.*									
			2012 claims data indicates a low									
			threshold of eligible professionals									
			reporting this measure via claims. CMS									
			intends to streamline the reporting									
			options available under the PQRS and									
			to eliminate reporting options that are									
			not widely used. For these reasons, we									
			are finalizing the removal of the claims-									
			based reporting option beginning in									
			2014.									
0416/		Effective Clinical Care	Diabetes Mellitus: Diabetic Foot and	APMA		X						
127			Ankle Care, Ulcer Prevention –									
			Evaluation of Footwear: Percentage of									
			patients aged 18 years and older with a									
			diagnosis of diabetes mellitus who were									

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting	Programs
			evaluated for proper footwear and sizing *The claims-based reporting option is no longer available for reporting this measure for 2014 and beyond.* 2012 claims data indicates a low threshold of eligible professionals reporting this measure via claims. CMS intends to streamline the reporting options available under the PQRS and to eliminate reporting options that are not widely used. For these reasons, we are finalizing the removal of the claims-based reporting option beginning in 2014.								
0421/ 128	69v2	Community/ Population Health	Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow- Up: Percentage of patients aged 18 years and older with a documented BMI during the current encounter or during the previous 6 months, AND when the BMI is outside of normal parameters, a follow-up plan is documented during the encounter or during the previous 6 months of the encounter Normal Parameters: Age 65 years and	CMS	X	X	X	X	X	MU2 ACO	

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality	Keporting Programs
			older BMI \geq 23 and $<$ 30; Age 18 – 64								
			years BMI \geq 18.5 and \leq 25								
			This measure was finalized for								
			inclusion in 2014 PQRS in the CY 2013								
			PFS Final Rule (see Table 95 at 77 FR								
0.4107	60.2	D. C. G. G.	69215).	G) (G	***	77	***		77	3.67	<u> </u>
0419/	68v3	Patient Safety	Documentation of Current	CMS	X	X	X		X	MU	J2
130			Medications in the Medical Record:								
			Percentage of visits for patients aged 18								
			years and older for which the eligible professional attests to documenting a								
			list of current medications using all								
			immediate resources available on the								
			date of the encounter. This list must								
			include ALL known prescriptions,								
			over-the-counters, herbals, and								
			vitamin/mineral/dietary (nutritional)								
			supplements AND <u>must</u> contain the								
			medications' name, dosage, frequency								
			and route of administration.								
			*The EHR-based reporting option is								
			available for reporting this measure								
			beginning in 2014.*								

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures	Other Onality	Reporting	Programs
			In an effort to align with the EHR Incentive Program, this measure will be reportable via EHR beginning in 2014. The alignment of measures contained within multiple CMS reporting programs eases the burden of reporting and encourages eligible professionals to submit quality clinical data on care provided for Medicare beneficiaries. Alignment also promotes a robust data source and consistency in analysis, which supports other quality programs within CMS. For the reasons previously stated, we are finalizing the addition of the EHR-based option beginning in 2014.									
0420/		Community/ Population Health	Pain Assessment and Follow-Up: Percentage of visits for patients aged 18 years and older with documentation of a pain assessment using a standardized tool(s) on each visit AND documentation of a follow-up plan when pain is present This measure was finalized for inclusion in 2014 PQRS in the CY 2013	CMS	X	X						

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
			PFS Final Rule (see Table 95 at 77 FR 69215).							
0418/	2v3	Community/ Population Health	Preventive Care and Screening: Screening for Clinical Depression and Follow-Up Plan: Percentage of patients aged 12 years and older screened for clinical depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen. *The EHR-based reporting option is available for reporting this measure beginning in 2014.* In an effort to align with the EHR Incentive Program, this measure will be reportable via EHR beginning in 2014. The alignment of measures contained within multiple CMS reporting programs eases the burden of reporting and encourages eligible professionals to submit quality clinical data on care provided for Medicare beneficiaries. Alignment also promotes a robust data source and consistency in analysis, which supports other quality programs within CMS. For the reasons previously stated, we are finalizing the addition of the EHR-based option beginning in 2014.	CMS	X	X	X	X		MU2 ACO
0650/		Effective Clinical Care	Melanoma: Continuity of Care –	AMA-		X				

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality	Reporting Programs
137			Recall System: Percentage of patients, regardless of age, with a current diagnosis of melanoma or a history of melanoma whose information was entered, at least once within a 12 month period, into a recall system that includes: • A target date for the next complete physical skin exam, AND • A process to follow up with patients who either did not make an appointment within the specified timeframe or who missed a scheduled appointment This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).	PCPI/NCQA							
N/A/ 138		Communication and Care Coordination	Melanoma: Coordination of Care: Percentage of patient visits, regardless of age, with a new occurrence of melanoma who have a treatment plan documented in the chart that was communicated to the physician(s) providing continuing care within 1	AMA- PCPI/NCQA		X					

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality	Reporting Programs
			month of diagnosis								
			This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR								
0566/		Effective Clinical Care	69215). Age-Related Macular Degeneration	AMA- PCPI/	X	X					
140		Effective Chinical Cure	(AMD): Counseling on Antioxidant Supplement: Percentage of patients aged 50 years and older with a diagnosis of age-related macular degeneration (AMD) or their caregiver(s) who were counseled within 12 months on the benefits and/or risks of the Age-Related Eye Disease Study (AREDS) formulation for preventing progression of AMD This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR	NCQA							
05(2)		C	69215).	AMA DCDI/	V	V				_	
0563/ 141		Communication and Care Coordination	Primary Open-Angle Glaucoma (POAG): Reduction of Intraocular Pressure (IOP) by 15% OR Documentation of a Plan of Care:	AMA- PCPI/ NCQA	X	X					

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality	Reporting Programs
			Percentage of patients aged 18 years and older with a diagnosis of primary open-angle glaucoma (POAG) whose glaucoma treatment has not failed (the most recent IOP was reduced by at least 15% from the pre- intervention level) OR if the most recent IOP was not reduced by at least 15% from the pre- intervention level, a plan of care was documented within 12 months This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR								
0051/142		Effective Clinical Care	Osteoarthritis (OA): Assessment for Use of Anti-Inflammatory or Analgesic Over-the-Counter (OTC) Medications: Percentage of patient visits for patients aged 21 years and older with a diagnosis of osteoarthritis (OA) with an assessment for use of anti-inflammatory or analgesic over- the-counter (OTC) medications This measure was finalized for	AMA-PCPI	X	X					

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting	Programs
			inclusion in 2014 PQRS in the CY 2013								
			PFS Final Rule (see Table 95 at 77 FR								
0384/	157v2	Person and Caregiver-	69215). Oncology: Medical and Radiation –	AMA-PCPI		X	X		X	MU2	
143	13/12	Centered Experience	Pain Intensity Quantified: Percentage	AWA-I CI I		Λ	Λ		Λ	WICZ	
		and Outcomes	of patient visits, regardless of patient								
			age, with a diagnosis of cancer								
			currently receiving chemotherapy or								
			radiation therapy in which pain								
			intensity is quantified								
			*The EHR-based reporting option is								
			available for reporting this measure								
			beginning in 2014.*								
			In an effort to align with the EHR								
			Incentive Program, this measure will be								
			reportable via EHR beginning in 2014.								
			The alignment of measures contained								
			within multiple CMS reporting								
			programs eases the burden of reporting								
			and encourages eligible professionals to								
			submit quality clinical data on care								
			provided for Medicare beneficiaries.								
			Alignment also promotes a robust data								
			source and consistency in analysis,								

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures	Other Quality	Reporting Programs
			which supports other quality programs within CMS. For the reasons previously stated, we are finalizing the addition of the EHR-based option beginning in 2014.								
0383/144		Person and Caregiver- Centered Experience and Outcomes	Oncology: Medical and Radiation – Plan of Care for Pain: Percentage of visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain with a documented plan of care to address pain This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).	AMA-PCPI		X			X		
0510/ 145		Patient Safety	Radiology: Exposure Time Reported for Procedures Using Fluoroscopy: Percentage of final reports for procedures using fluoroscopy that include documentation of radiation exposure or exposure time This measure was finalized for inclusion in 2014 PQRS in the CY 2013	AMA- PCPI/ NCQA	X	X					

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures	Other Quality	Reporting	Programs
			PFS Final Rule (see Table 95 at 77 FR 69215).									
0508/ 146		Efficiency and Cost Reduction	Radiology: Inappropriate Use of "Probably Benign" Assessment Category in Mammography Screening: Percentage of final reports for screening mammograms that are classified as "probably benign" This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).	AMA- PCPI/ NCQA	X	X						
N/A/ 147		Communication and Care Coordination	Nuclear Medicine: Correlation with Existing Imaging Studies for All Patients Undergoing Bone Scintigraphy: Percentage of final reports for all patients, regardless of age, undergoing bone scintigraphy that include physician documentation of correlation with existing relevant imaging studies (e.g., x-ray, MRI, CT, etc.) that were performed This measure was finalized for inclusion in 2014 PQRS in the CY 2013	AMA-PCPI	X	X						

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures	Other Quality	Reporting Programs
			PFS Final Rule (see Table 95 at 77 FR 69215).								
0322/ 148		Efficiency and Cost Reduction	Back Pain: Initial Visit: The percentage of patients aged 18 through 79 years with a diagnosis of back pain or undergoing back surgery who had back pain and function assessed during the initial visit to the clinician for the episode of back pain This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).	NCQA					X		
0319/149		Effective Clinical Care	Back Pain: Physical Exam: Percentage of patients aged 18 through 79 years with a diagnosis of back pain or undergoing back surgery who received a physical examination at the initial visit to the clinician for the episode of back pain This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).	NCQA					X		

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality	Reporting Programs
0314/ 150		Effective Clinical Care	Back Pain: Advice for Normal Activities: The percentage of patients aged 18 through 79 years with a diagnosis of back pain or undergoing back surgery who received advice for normal activities at the initial visit to the clinician for the episode of back pain	NCQA					X		
			This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).								
0313/ 151		Effective Clinical Care	Back Pain: Advice Against Bed Rest: The percentage of patients aged 18 through 79 years with a diagnosis of back pain or undergoing back surgery who received advice against bed rest lasting four days or longer at the initial visit to the clinician for the episode of back pain This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).	NCQA					X		

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures	Other Quality	Reporting Programs	1 1 0 St will
0101/ 154		Patient Safety	Falls: Risk Assessment: Percentage of patients aged 65 years and older with a history of falls who had a risk assessment for falls completed within 12 months This measure was finalized for inclusion in 2014 PORS in the CV 2013	AMA- PCPI/ NCQA	X	X						
			inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).									
0101/		Communication and	Falls: Plan of Care: Percentage of	AMA- PCPI/	X	X						-
155		Care Coordination	patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months	NCQA								
			This measure was finalized for									
			inclusion in 2014 PQRS in the CY 2013									
			PFS Final Rule (see Table 95 at 77 FR 69215).									
0382/ 156		Patient Safety	Oncology: Radiation Dose Limits to Normal Tissues: Percentage of patients, regardless of age, with a	AMA-PCPI	X	X						
			diagnosis of pancreatic or lung cancer receiving 3D conformal radiation therapy with documentation in medical									
			record that radiation dose limits to									

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality	Keporting Programs
			normal tissues were established prior to the initiation of a course of 3D conformal radiation for a minimum of two tissues								
			This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).								
0455/ 157		Patient Safety	Thoracic Surgery: Recording of Clinical Stage Prior to Lung Cancer or Esophageal Cancer Resection: Percentage of surgical patients aged 18 years and older undergoing resection for lung or esophageal cancer who had clinical staging provided prior to surgery This measure was finalized for inclusion in 2014 PQRS in the CY 2013	STS	X	X					
0404/		Effective Clinical Care	PFS Final Rule (see Table 95 at 77 FR 69215). HIV/AIDS: CD4+ Cell Count or CD4+ Percentage Performed: Percentage of patients aged 6 months and older with a diagnosis of	AMA- PCPI/ NCQA		X			X		

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality	Keporting Programs
			HIV/AIDS for whom a CD4+ cell								
			count or CD4+ cell percentage was								
			performed at least once every 6 months								
			This measure was finalized for								
			inclusion in 2014 PQRS in the CY 2013								
			PFS Final Rule (see Table 95 at 77 FR								
			69215).								
0405/	52v2	Effective Clinical Care	HIV/AIDS: Pneumocystis jiroveci	NCQA		X	X		X	MU	J2
160			pneumonia (PCP) prophylaxis:								
			Percentage of patients aged 6 weeks								
			and older with a diagnosis of								
			HIV/AIDS who were prescribed								
			Pneumocystis jiroveci pneumonia								
			(PCP) prophylaxis								
			*The EHR-based reporting option is								
			available for reporting this measure								
			beginning in 2014.*								
			In an effort to align with the EHR								
			Incentive Program, this measure will be								
			reportable via EHR beginning in 2014.								
			The alignment of measures contained								
			within multiple CMS reporting								
			programs eases the burden of reporting								

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Renorting	reporting Programs
			and encourages eligible professionals to submit quality clinical data on care provided for Medicare beneficiaries. Alignment also promotes a robust data source and consistency in analysis, which supports other quality programs within CMS. For the reasons previously stated, we are finalizing the addition of the EHR-based option beginning in 2014.								
0056/ 163	123v2	Effective Clinical Care	Diabetes: Foot Exam: Percentage of patients aged 18-75 years of age with diabetes who had a foot exam during the measurement period. This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).	NCQA	X	X	X		X	MU	2
0129/ 164		Effective Clinical Care	Coronary Artery Bypass Graft (CABG): Prolonged Intubation: Percentage of patients aged 18 years and older undergoing isolated CABG surgery who require postoperative intubation > 24 hours	STS		X			X		

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting	Programs
			This measure was finalized for								
			inclusion in 2014 PQRS in the CY 2013								
			PFS Final Rule (see Table 95 at 77 FR 69215).								
0130/		Effective Clinical Care	Coronary Artery Bypass Graft	STS		X			X		
165			(CABG): Deep Sternal Wound								
			Infection Rate: Percentage of patients								
			aged 18 years and older undergoing								
			isolated CABG surgery who, within 30								
			days postoperatively, develop deep								
			sternal wound infection involving								
			muscle, bone, and/or mediastinum								
			requiring operative intervention								
			This measure was finalized for								
			inclusion in 2014 PQRS in the CY 2013								
			PFS Final Rule (see Table 95 at 77 FR								
_			69215).								
0131/		Effective Clinical Care	Coronary Artery Bypass Graft	STS		X			X		
166			(CABG): Stroke: Percentage of								
			patients aged 18 years and older								
			undergoing isolated CABG surgery								
			who have a postoperative stroke (i.e.,								
			any confirmed neurological deficit of								
			abrupt onset caused by a disturbance in								
			blood supply to the brain) that did not								

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
			resolve within 24 hours This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).							
0114/ 167		Effective Clinical Care	Coronary Artery Bypass Graft (CABG): Postoperative Renal Failure: Percentage of patients aged 18 years and older undergoing isolated CABG surgery (without pre-existing renal failure) who develop postoperative renal failure or require dialysis This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).	STS		X			X	
0115/ 168		Effective Clinical Care	Coronary Artery Bypass Graft (CABG): Surgical Re-Exploration: Percentage of patients aged 18 years and older undergoing isolated CABG surgery who require a return to the operating room (OR) during the current hospitalization for mediastinal bleeding	STS		X			X	

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality	Keporting Programs
			with or without tamponade, graft occlusion, valve dysfunction, or other cardiac reason								
			This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).								
0116/ 169		Effective Clinical Care	Coronary Artery Bypass Graft (CABG): Antiplatelet Medications at Discharge: Percentage of patients aged 18 years and older undergoing isolated CABG surgery who were discharged on antiplatelet medication This measure was finalized for	STS		X			X		
			inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).								
0117/ 170		Effective Clinical Care	Coronary Artery Bypass Graft (CABG): Beta-Blockers Administered at Discharge: Percentage of patients aged 18 years and older undergoing isolated CABG surgery who were discharged on beta-	STS		X			X		

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
			blockers							
			This measure was finalized for							
			inclusion in 2014 PQRS in the CY 2013							
			PFS Final Rule (see Table 95 at 77 FR							
			69215).							
0118/		Effective Clinical Care	Coronary Artery Bypass Graft	STS		X			X	
171			(CABG): Anti-Lipid Treatment at							
			Discharge: Percentage of patients aged							
			18 years and older undergoing isolated							
			CABG surgery who were discharged on							
			a statin or other lipid-lowering regimen							
			This measure was finalized for							
			inclusion in 2014 PQRS in the CY 2013							
			PFS Final Rule (see Table 95 at 77 FR							
			69215).							
0259/		Effective Clinical Care	Hemodialysis Vascular Access	SVS	X	X				
172			Decision-Making by Surgeon to							
			Maximize Placement of Autogenous							
			Arterial Venous (AV) Fistula:							
			Percentage of patients aged 18 years							
			and older with a diagnosis of advanced							
			Chronic Kidney Disease (CKD) (stage							
			3, 4 or 5) or End Stage Renal Disease							
			(ESRD) requiring hemodialysis							

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures	Other Quality Reporting
			vascular access documented by surgeon to have received autogenous AV fistula This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).							
AQA adopted/ 173		Community/ Population Health	Preventive Care and Screening: Unhealthy Alcohol Use – Screening: Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method within 24 months	AMA-PCPI		X			X	
			The claims-based and EHR-based reporting options have been removed from this measure for 2014 PQRS. This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).							
AQA adopted/ 176		Effective Clinical Care	Rheumatoid Arthritis (RA): Tuberculosis Screening: Percentage of patients aged 18 years and older with a	AMA- PCPI		X			X	

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality	Reporting Programs
			diagnosis of rheumatoid arthritis (RA) who have documentation of a tuberculosis (TB) screening performed and results interpreted within 6 months prior to receiving a first course of therapy using a biologic diseasemodifying anti-rheumatic drug (DMARD)								
			The claims-based reporting option is no longer available for reporting this measure for 2014 and beyond.								
			2012 claims data indicates a low threshold of eligible professionals reporting this measure via claims. CMS intends to streamline the reporting options available under the PQRS and to eliminate reporting options that are not widely used. For these reasons, we are finalizing the removal of the claims-based option for 2014 and beyond.								
AQA adopted/ 177		Effective Clinical Care	Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity: Percentage of patients aged 18 years and older with a diagnosis of	AMA- PCPI		X			X		

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality	Reporting Programs
			rheumatoid arthritis (RA) who have an assessment and classification of disease activity within 12 months								
			The claims-based reporting option is no longer available for reporting this measure for 2014 and beyond.								
			2012 claims data indicates a low threshold of eligible professionals reporting this measure via claims. CMS								
			intends to streamline the reporting options available under the PQRS and to eliminate reporting options that are not widely used. For these reasons, we								
			are finalizing the removal of the claimsbased option for 2014 and beyond.								
AQA adopted/ 178		Effective Clinical Care	Rheumatoid Arthritis (RA): Functional Status Assessment: Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) for whom a functional status assessment was performed at least once within 12 months	AMA- PCPI		X			X		

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality	Reporting Programs
			The claims-based reporting option is no longer available for reporting this measure for 2014 and beyond. 2012 claims data indicates a low threshold of eligible professionals reporting this measure via claims. CMS intends to streamline the reporting options available under the PQRS and to eliminate reporting options that are not widely used. For these reasons, we are finalizing the removal of the claims-based option for 2014 and beyond.								
AQA adopted/ 179		Effective Clinical Care	Rheumatoid Arthritis (RA): Assessment and Classification of Disease Prognosis: Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have an assessment and classification of disease prognosis at least once within 12 months *The claims-based reporting option is no longer available for reporting this measure for 2014 and beyond.*	AMA- PCPI		X			X		

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality	Reporting Programs
AQA		Communication and	2012 claims data indicates a low threshold of eligible professionals reporting this measure via claims. CMS intends to streamline the reporting options available under the PQRS and to eliminate reporting options that are not widely used. For these reasons, we are finalizing the removal of the claims-based option for 2014 and beyond. Rheumatoid Arthritis (RA):	AMA- PCPI		X			X		
adopted/ 180		Care Coordination	Rheumatoid Arthritis (RA): Glucocorticoid Management: Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have been assessed for glucocorticoid use and, for those on prolonged doses of prednisone ≥ 10 mg daily (or equivalent) with improvement or no change in disease activity, documentation of glucocorticoid management plan within 12 months *The claims-based reporting option is no longer available for reporting this measure for 2014 and beyond.*	AMA- PCPI		X			X		

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure	Claims	Registry	EHR	GPRO (Web Interface)*	Measures	Other Ouality	Reporting	Programs
			CMS would like to note that although									
			this measure was not listed in our									
			proposal as having a reporting option									
			change, we are finalizing it as registry-									
			only beginning in 2014. CMS believes									
			it necessary to maintain consistency of									
			clinically-related measures available									
			within a particular reporting option;									
			therefore, we are eliminating this									
			measure from the claims-based									
			reporting option. 2012 claims data									
			indicates a low threshold of eligible									
			professionals reporting this measure via									
			claims. CMS intends to streamline the									
			reporting options available under the									
			PQRS and to eliminate reporting									
			options that are not widely used.									
			Eligible professionals who report this									
			measure will still have an opportunity									
			to participate in PQRS using the									
			registry-based reporting option. For									
			these reasons, we are finalizing the									
			removal of the claims-based option for									
			this measure beginning in 2014.									
AQA		Patient Safety	Elder Maltreatment Screen and	CMS	X	X						

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality	Reporting Programs
adopted/ 181			Follow-Up Plan: Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).								
AQA adopted/ 182		Communication and Care Coordination	Functional Outcome Assessment: Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR	CMS	X	X					

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality	Reporting Programs
			69215).								
0399/		Community/Population	Hepatitis C: Hepatitis A Vaccination	AMA-PCPI		X			X		
183		Health	in Patients with Hepatitis C Virus								
			(HCV): Percentage of patients aged 18								
			years and older with a diagnosis of								
			chronic hepatitis C who have received								
			at least one injection of hepatitis A								
			vaccine, or who have documented								
			immunity to hepatitis A								
			*The claims-based reporting option is								
			no longer available for reporting this								
			measure for 2014 and beyond.*								
			CMS would like to note that although								
			this measure was not listed in our								
			proposal as having a reporting option								
			change, we are finalizing it as registry-								
			only beginning in 2014. CMS believes								
			it necessary to maintain consistency of								
			clinically-related measures available								
			within a particular reporting option;								
			therefore, we are eliminating this								
			measure from the claims-based								
			reporting option. 2012 claims data								
			indicates a low threshold of eligible								

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality	Reporting Programs
			professionals reporting this measure via claims. CMS intends to streamline the reporting options available under the PQRS and to eliminate reporting options that are not widely used. Eligible professionals who report this measure will still have an opportunity to participate in PQRS using the registry-based reporting option. For these reasons, we are finalizing the removal of the claims-based option for this measure beginning in 2014.								
0659/ 185		Communication and Care Coordination	Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use: Percentage of patients aged 18 years and older receiving a surveillance colonoscopy, with a history of a prior adenomatous polyp(s) in previous colonoscopy findings, who had an interval of 3 or more years since their last colonoscopy This measure was finalized for	AMA- PCPI/ NCQA	X	X					

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures	Other Quality	Reporting Programs
			inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).								
N/A/ 187		Effective Clinical Care	Stroke and Stroke Rehabilitation: Thrombolytic Therapy: Percentage of patients aged 18 years and older with a diagnosis of acute ischemic stroke who arrive at the hospital within two hours of time last known well and for whom IV t-PA was initiated within three hours of time last known well This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).	AHA/ ASA/ TJC		X					
0565/ 191	133v2	Effective Clinical Care	Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery: Percentage of patients aged 18 years and older with a diagnosis of uncomplicated cataract who had cataract surgery and no significant ocular conditions impacting the visual outcome of surgery and had best-corrected visual acuity of 20/40 or better (distance or near) achieved	AMA- PCPI/ NCQA		X	X		X	M	U2

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality	Reporting Programs
			within 90 days following the cataract surgery *The EHR-based reporting option is available for reporting this measure beginning in 2014.* In an effort to align with the EHR Incentive Program, this measure will be reportable via EHR beginning in 2014. The alignment of measures contained within multiple CMS reporting programs eases the burden of reporting and encourages eligible professionals to submit quality clinical data on care provided for Medicare beneficiaries. Alignment also promotes a robust data source and consistency in analysis, which supports other quality programs								
0.5644	122.2		within CMS. For these reasons, we are finalizing the addition of the EHR-based reporting option for this measure beginning in 2014.	AMA DODY		V	T.		V		
0564/ 192	132v2	Patient Safety	Cataracts: Complications within 30 Days Following Cataract Surgery Requiring Additional Surgical	AMA- PCPI/ NCQA		X	X		X	MU	J2

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures	Other Quality	Reporting	Programs
			Procedures: Percentage of patients aged 18 years and older with a									
			diagnosis of uncomplicated cataract									
			who had cataract surgery and had any									
			of a specified list of surgical procedures									
			in the 30 days following cataract									
			surgery which would indicate the									
			occurrence of any of the following									
			major complications: retained nuclear fragments, endophthalmitis, dislocated									
			or wrong power IOL, retinal									
			detachment, or wound dehiscence									
			demonstration, or mountained and									
			*The EHR-based reporting option is									
			available for reporting this measure									
			beginning in 2014.*									
			T CC II									
			In an effort to align with the EHR									
			Incentive Program, this measure will be reportable via EHR beginning in 2014.									
			The alignment of measures contained									
			within multiple CMS reporting									
			programs eases the burden of reporting									
			and encourages eligible professionals to									
			submit quality clinical data on care									
			provided for Medicare beneficiaries.									

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures	Other Quality	Reporting Programs
			Alignment also promotes a robust data source and consistency in analysis, which supports other quality programs within CMS. For these reasons, we are finalizing the addition of the EHR-based reporting option for this measure beginning in 2014.								
0454/193		Patient Safety	Perioperative Temperature Management: Percentage of patients, regardless of age, undergoing surgical or therapeutic procedures under general or neuraxial anesthesia of 60 minutes duration or longer, except patients undergoing cardiopulmonary bypass, for whom either active warming was used intraoperatively for the purpose of maintaining normothermia, OR at least one body temperature equal to or greater than 36 degrees Centigrade (or 96.8 degrees Fahrenheit) was recorded within the 30 minutes immediately before or the 15 minutes immediately after anesthesia end time This measure was finalized for inclusion in 2014 PQRS in the CY 2013	AMA-PCPI	X	X					

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality	Reporting Programs
			PFS Final Rule (see Table 95 at 77 FR 69215).								
0386/ 194		Effective Clinical Care	Oncology: Cancer Stage Documented: Percentage of patients, regardless of age, with a diagnosis of cancer who are seen in the ambulatory setting who have a baseline American Joint Committee on Cancer (AJCC) cancer stage or documentation that the cancer is metastatic in the medical record at least once during the 12 month reporting period This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).	AMA- PCPI/ ASCO	X	X			X		
0507/ 195		Effective Clinical Care	Radiology: Stenosis Measurement in Carotid Imaging Reports: Percentage of final reports for carotid imaging studies (neck magnetic resonance angiography [MRA], neck computed tomography angiography [CTA], neck duplex ultrasound, carotid angiogram) performed that include direct or indirect reference to measurements of distal	AMA- PCPI/ NCQA	X	X					

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
			internal carotid diameter as the denominator for stenosis measurement							
			This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).							
0074/197		Effective Clinical Care	Coronary Artery Disease (CAD): Lipid Control: Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who have a LDL-C result < 100 mg/dL OR patients who have a LDL-C result ≥ 100 mg/dL and have a documented plan of care to achieve LDL-C < 100 mg/dL, including at a minimum the prescription of a statin *The EHR-based reporting mechanism is no longer available for reporting this measure for 2014 and beyond.* In an effort to align with the EHR	AMA- PCPI/ ACCF/AHA		X		X	X	ACO
			-							

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality	Reporting Programs
			in 2014. The alignment of measures contained within multiple CMS reporting programs eases the burden of reporting and encourages eligible professionals to submit quality clinical data on care provided for Medicare beneficiaries. Alignment also promotes a robust data source and consistency in analysis, which supports other quality programs within CMS. For the reasons previously stated, we are finalizing the removal of the EHR-based option beginning in 2014.								
0079/ 198		Effective Clinical Care	Heart Failure: Left Ventricular Ejection Fraction (LVEF) Assessment: Percentage of patients aged 18 years and older with a diagnosis of heart failure for whom the quantitative or qualitative results of a recent or prior [any time in the past] LVEF assessment is documented within a 12 month period This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR	AMA- PCPI/ ACCF/AHA		X			X		

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
			69215).							
0068/	164v2	Effective Clinical Care	Ischemic Vascular Disease (IVD):	NCQA	X	X	X	X	X	MU2
204			Use of Aspirin or Another							ACO
			Antithrombotic: Percentage of patients							Million
			18 years of age and older who were							Hearts
			discharged alive for acute myocardial							
			infarction (AMI), coronary artery							
			bypass graft (CABG) or percutaneous							
			coronary interventions (PCI) in the 12							
			months prior to the measurement							
			period, or who had an active diagnosis							
			of ischemic vascular disease (IVD)							
			during the measurement period, and							
			who had documentation of use of							
			aspirin or another antithrombotic during							
			the measurement period.							
			This measure was finalized for							
			inclusion in 2014 PQRS in the CY 2013							
			PFS Final Rule (see Table 95 at 77 FR							
			69215).							
0409/205		Effective Clinical Care	HIV/AIDS: Sexually Transmitted	AMA-PCPI/		X			X	
			Disease Screening for Chlamydia,	NCQA						
			Gonorrhea, and Syphilis: Percentage of patients aged 13 years							
			and older with a diagnosis of							
			HIV/AIDS for whom chlamydia,							
			THY/AIDS for whom chamyula,							

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality	Keporting Programs
			gonorrhea and syphilis screenings were performed at least once since the diagnosis of HIV infection								
			This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).								
0422/		Communication and	Functional Deficit: Change in Risk-	FOTO		X					
217		Care Coordination	Adjusted Functional Status for Patients with Knee Impairments: Percentage of patients aged 18 or older that receive treatment for a functional deficit secondary to a diagnosis that affects the knee in which the change in their Risk-Adjusted Functional Status is measured This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).								
0423/		Communication and	Functional Deficit: Change in Risk-	FOTO		X					
218		Care Coordination	Adjusted Functional Status for								
			Patients with Hip Impairments: Percentage of patients aged 18 or older								
			referrage of patients aged to of older								

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality	Reporting Programs
			that receive treatment for a functional deficit secondary to a diagnosis that affects the hip in which the change in their Risk-Adjusted Functional Status is measured								
			This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).								
0424/		Communication and	Functional Deficit: Change in Risk-	FOTO		X					
219		Care Coordination	Adjusted Functional Status for								
			Patients with Lower Leg, Foot or Ankle Impairments: Percentage of patients aged 18 or older that receive treatment for a functional deficit secondary to a diagnosis that affects the lower leg, foot or ankle in which the change in their Risk-Adjusted Functional Status is measured This measure was finalized for								
			inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).								
0425/		Communication and	Functional Deficit: Change in Risk-	FOTO		X					

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure	Claims	Registry	EHR	GPRO (Web Interface)*	Measures	Other Quality	Reporting	Programs
220		Care Coordination	Adjusted Functional Status for Patients with Lumbar Spine Impairments: Percentage of patients aged 18 or older that receive treatment for a functional deficit secondary to a diagnosis that affects the lumbar spine in which the change in their Risk-Adjusted Functional Status is measured This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).									
0426/221		Communication and Care Coordination	Functional Deficit: Change in Risk-Adjusted Functional Status for Patients with Shoulder Impairments: Percentage of patients aged 18 or older that receive treatment for a functional deficit secondary to a diagnosis that affects the shoulder in which the change in their Risk-Adjusted Functional Status is measured This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR	FOTO		X						

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures	Other Quality	Reporting Programs
			69215).								
0427/		Communication and	Functional Deficit: Change in Risk-	FOTO		X					
222		Care Coordination	Adjusted Functional Status for								
			Patients with Elbow, Wrist or Hand								
			Impairments: Percentage of patients								
			aged 18 or older that receive treatment								
			for a functional deficit secondary to a								
			diagnosis that affects the elbow, wrist								
			or hand in which the change in their								
			Risk-Adjusted Functional Status is								
			measured								
			This measure was finalized for								
			inclusion in 2014 PQRS in the CY 2013								
			PFS Final Rule (see Table 95 at 77 FR								
			69215).								
0428/		Communication and	Functional Deficit: Change in Risk-	FOTO		X					
223		Care Coordination	Adjusted Functional Status for								
			Patients with Neck, Cranium,								
			Mandible, Thoracic Spine, Ribs, or								
			Other General Orthopedic								
			Impairments: Percentage of patients								
			aged 18 or older that receive treatment								
			for a functional deficit secondary to a								
			diagnosis that affects the neck, cranium,								
			mandible, thoracic spine, ribs, or other								

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality	Reporting Programs
			general orthopedic impairment in which the change in their Risk-Adjusted Functional Status is measured This measure was finalized for								
			inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).								
0562/ 224		Efficiency and Cost Reduction	Melanoma: Overutilization of Imaging Studies in Melanoma: Percentage of patients, regardless of age, with a current diagnosis of stage 0 through IIC melanoma or a history of melanoma of any stage, without signs or symptoms suggesting systemic spread, seen for an office visit during the one-year measurement period, for whom no diagnostic imaging studies were ordered	AMA- PCPI/ NCQA		X					
			This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).								
0509/ 225		Communication and Care Coordination	Radiology: Reminder System for Mammograms: Percentage of patients	AMA- PCPI/ NCQA	X	X					

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Renorting	Reporting Programs
			aged 40 years and older undergoing a screening mammogram whose information is entered into a reminder system with a target due date for the next mammogram This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).								
0028/226	138v2	Community/ Population Health	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).	AMA-PCPI	X	X	X	X	X	MU ACO Mill Hea	O lion
N/A/ 228		Effective Clinical Care	Heart Failure (HF): Left Ventricular Function (LVF) Testing: Percentage	CMS		X					

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality	Reporting Programs
			of patients 18 years and older with Left Ventricular Function (LVF) testing documented as being performed within the previous 12 months or LVF testing performed prior to discharge for patients who are hospitalized with a principal diagnosis of Heart Failure (HF) during the reporting period This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).								
N/A/ 231		Effective Clinical Care	Asthma: Tobacco Use: Screening - Ambulatory Care Setting: Percentage of patients aged 5 through 64 years with a diagnosis of asthma (or their primary caregiver) who were queried about tobacco use and exposure to second hand smoke within their home environment at least once during the one-year measurement period This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR	AMA- PCPI/ NCQA	X	X			X		

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality	Reporting Programs
			69215).								
N/A/ 232		Effective Clinical Care	Asthma: Tobacco Use: Intervention - Ambulatory Care Setting: Percentage of patients aged 5 through 64 years with a diagnosis of asthma who were identified as tobacco users (or their primary caregiver) who received tobacco cessation intervention at least once during the one-year measurement period This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR	AMA- PCPI/NCQA	X	X			X		
0457/233		Effective Clinical Care	Thoracic Surgery: Recording of Performance Status Prior to Lung or Esophageal Cancer Resection: Percentage of patients aged 18 years and older undergoing resection for lung or esophageal cancer for whom performance status was documented and reviewed within 2 weeks prior to surgery This measure was finalized for	STS		X					

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
			inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).							
0458/234		Patient Safety	Thoracic Surgery: Pulmonary Function Tests Before Major Anatomic Lung Resection (Pneumonectomy, Lobectomy, or Formal Segmentectomy): Percentage of thoracic surgical patients aged 18 years and older undergoing at least one pulmonary function test within 12 months prior to a major lung resection (pneumonectomy, lobectomy, or formal segmentectomy) This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).	STS		X				
0018/236	165v2	Effective Clinical Care	Controlling High Blood Pressure: Percentage of patients 18-85 years of age who had a diagnosis of hypertension whose blood pressure was adequately controlled (<140/90 mmHg) during the measurement period.	NCQA	X	X	X	X	X	MU2 ACO Million Hearts

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
			This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).							
0022/238	156v2	Patient Safety	Use of High-Risk Medications in the Elderly: Percentage of patients 66 years of age and older who were ordered high-risk medications. Two rates are reported. a. Percentage of patients who were ordered at least one high-risk medication. b. Percentage of patients who were ordered at least two different high-risk medications. This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).	NCQA			X			MU2
0024/239	155v2	Community/Population Health	Weight Assessment and Counseling for Nutrition and Physical Activity for Children and Adolescents: Percentage of patients 3-17 years of age who had an outpatient visit with a Primary Care Physician (PCP) or Obstetrician/Gynecologist (OB/GYN) and who had evidence of the following during the measurement period. Three rates are reported.	NCQA			X			MU2

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure	Claims	Registry	EHR	GPRO (Web Interface)*	Measures	Other Ouality	Reporting	Programs
			- Percentage of patients with height, weight, and body mass index (BMI) percentile documentation - Percentage of patients with counseling for nutrition - Percentage of patients with counseling for physical activity This measure was finalized for									
			inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).									
0038/240	117v2	Community/Population Health	Childhood Immunization Status: Percentage of children 2 years of age who had four diphtheria, tetanus and acellular pertussis (DTaP); three polio (IPV), one measles, mumps and rubella (MMR); three H influenza type B (HiB); three hepatitis B (Hep B); one chicken pox (VZV); four pneumococcal conjugate (PCV); one hepatitis A (Hep A); two or three rotavirus (RV); and two influenza (flu) vaccines by their second birthday.	NCQA			X			N	AU2	

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
			This measure was finalized for							
			inclusion in 2014 PQRS in the CY 2013							
			PFS Final Rule (see Table 95 at 77 FR 69215).							
0075/	182v3	Effective Clinical Care	Ischemic Vascular Disease (IVD):	NCQA	X	X	X	X	X	MU2
241			Complete Lipid Panel and LDL							ACO
			Control: Percentage of patients 18							Million
			years of age and older who were							Hearts
			discharged alive for acute myocardial							
			infarction (AMI), coronary artery							
			bypass graft (CABG) or percutaneous							
			coronary interventions (PCI) in the 12							
			months prior to the measurement							
			period, or who had an active diagnosis							
			of ischemic vascular disease (IVD)							
			during the measurement period, and							
			who had a complete lipid profile							
			performed during the measurement							
			period and whose LDL-C was							
			adequately controlled (< 100 mg/dL).							
			This measure was finalized for							
			inclusion in 2014 PQRS in the CY 2013							
			PFS Final Rule (see Table 95 at 77 FR							
			69215).							
N/A/		Effective Clinical Care	Coronary Artery Disease (CAD):	AMA- PCPI/		X			X	

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality	Reporting Programs
242			Symptom Management: Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period with results of an evaluation of level of activity and an assessment of whether anginal symptoms are present or absent with appropriate management of anginal symptoms within a 12 month period	ACCF/AHA							
			This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).								
0643/243		Effective Clinical Care	Cardiac Rehabilitation Patient Referral from an Outpatient Setting: Percentage of patients evaluated in an outpatient setting who within the previous 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA)	ACCF-AHA		X					

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Renorting	reporting Programs
			and have not already participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program for the qualifying event/diagnosis who were referred to a CR program This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR								
404		Effective Clinical Care	69215). Chronic Wound Care: Use of Wound	AMA- PCPI/	X	X					
AQA adopted/ 245		Effective Chilical Care	Surface Culture Technique in Patients with Chronic Skin Ulcers (Overuse Measure): Percentage of patient visits for those patients aged 18 years and older with a diagnosis of chronic skin ulcer without the use of a wound surface culture technique This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).	NCQA	A	A					
AQA		Effective Clinical Care	Chronic Wound Care: Use of Wet to	AMA- PCPI/	X	X					
adopted/			Dry Dressings in Patients with	NCQA							

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality	Reporting Programs
246			Chronic Skin Ulcers (Overuse Measure): Percentage of patient visits for those patients aged 18 years and older with a diagnosis of chronic skin ulcer without a prescription or recommendation to use wet to dry dressings								
			This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).								
AQA adopted/ 247		Effective Clinical Care	Regarding Psychosocial and Pharmacologic Treatment Options for Alcohol Dependence: Percentage of patients aged 18 years and older with a diagnosis of current alcohol dependence who were counseled regarding psychosocial AND pharmacologic treatment options for alcohol dependence within the 12- month reporting period	AMA- PCPI/ NCQA	X	X					
			This measure was finalized for inclusion in 2014 PQRS in the CY 2013								

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures	Other Quality	Reporting	Programs
			PFS Final Rule (see Table 95 at 77 FR 69215).									
AQA adopted/ 248		Effective Clinical Care	Substance Use Disorders: Screening for Depression Among Patients with Substance Abuse or Dependence: Percentage of patients aged 18 years and older with a diagnosis of current substance abuse or dependence who were screened for depression within the 12-month reporting period This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).	AMA- PCPI/ NCQA	X	X						
N/A/ 249		Effective Clinical Care	Barrett's Esophagus: Percentage of esophageal biopsy reports that document the presence of Barrett's mucosa that also include a statement about dysplasia This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).	CAP	X	X						
N/A/		Effective Clinical Care	Radical Prostatectomy Pathology	CAP	X	X						

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality	Reporting Programs
250			Reporting: Percentage of radical prostatectomy pathology reports that include the pT category, the pN category, the Gleason score and a statement about margin status								
			This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).								
N/A/ 251		Effective Clinical Care	Immunohistochemical (IHC) Evaluation of Human Epidermal Growth Factor Receptor 2 Testing (HER2) for Breast Cancer Patients: This is a measure based on whether quantitative evaluation of Human Epidermal Growth Factor Receptor 2 Testing (HER2) by immunohistochemistry (IHC) uses the system recommended in the ASCO/CAP Guidelines for Human Epidermal Growth Factor Receptor 2 Testing in breast cancer This measure was finalized for	CAP	X	X					
			inclusion in 2014 PQRS in the CY 2013								

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web	Intertace)* Measures	Groups	Other Quality	Reporting Programs
			PFS Final Rule (see Table 95 at 77 FR 69215).									
0651/ 254		Effective Clinical Care	Ultrasound Determination of Pregnancy Location for Pregnant Patients with Abdominal Pain: Percentage of pregnant female patients aged 14 to 50 who present to the emergency department (ED) with a chief complaint of abdominal pain or vaginal bleeding who receive a trans-abdominal or trans- vaginal ultrasound to determine pregnancy location This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).	ACEP	X	X						
0652/ 255		Effective Clinical Care	Rh Immunoglobulin (Rhogam) for Rh-Negative Pregnant Women at Risk of Fetal Blood Exposure: Percentage of Rh-negative pregnant women aged 14-50 years at risk of fetal blood exposure who receive Rh-Immunoglobulin (Rhogam) in the emergency department (ED)	ACEP	X	X						

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [*]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality	Reporting Programs
			This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).								
N/A/ 257		Effective Clinical Care	Statin Therapy at Discharge after Lower Extremity Bypass (LEB): Percentage of patients aged 18 years and older undergoing infra-inguinal lower extremity bypass who are prescribed a statin medication at discharge This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).	SVS		X					
N/A/ 258		Communication and Care Coordination	Rate of Open Repair of Small or Moderate Non-Ruptured Abdominal Aortic Aneurysms (AAA) without Major Complications (Discharged to Home by Post-Operative Day #7): Percent of patients undergoing open repair of small or moderate sized non- ruptured abdominal aortic aneurysms who do not experience a major	SVS		X					

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality	Reporting Programs
			complication (discharge to home no later than post-operative day #7)								
			This measure was finalized for								
			inclusion in 2014 PQRS in the CY 2013								
			PFS Final Rule (see Table 95 at 77 FR 69215).								
N/A/		Communication and	Rate of Endovascular Aneurysm	SVS		X					
259		Care Coordination	Repair (EVAR) of Small or Moderate								
			Non-Ruptured Abdominal Aortic								
			Aneurysms (AAA) without Major								
			Complications (Discharged to Home								
			by Post-Operative Day #2): Percent of								
			patients undergoing endovascular repair								
			of small or moderate non-ruptured								
			abdominal aortic aneurysms (AAA) that								
			do not experience a major complication (discharged to home no later than post-								
			operative day #2)								
			This measure was finalized for								
			inclusion in 2014 PQRS in the CY 2013								
			PFS Final Rule (see Table 95 at 77 FR 69215).								
N/A/		Communication and	Rate of Carotid Endarterectomy	SVS		X					
260		Care Coordination	(CEA) for Asymptomatic Patients,								

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality	Reporting Programs
			without Major Complications								
			(Discharged to Home by Post-								
			Operative Day #2): Percent of								
			asymptomatic patients undergoing CEA								
			who are discharged to home no later								
			than post-operative day #2								
			This measure was finalized for								
			inclusion in 2014 PQRS in the CY 2013								
			PFS Final Rule (see Table 95 at 77 FR								
			69215).								
N/A/		Communication and	Referral for Otologic Evaluation for	AQC	X	X					
261		Care Coordination	Patients with Acute or Chronic								
			Dizziness: Percentage of patients aged								
			birth and older referred to a physician								
			(preferably a physician specially trained								
			in disorders of the ear) for an otologic								
			evaluation subsequent to an audiologic								
			evaluation after presenting with acute								
			or chronic dizziness								
			This measure was finalized for								
			inclusion in 2014 PQRS in the CY 2013								
			PFS Final Rule (see Table 95 at 77 FR								
			69215).								
N/A/		Patient Safety	Image Confirmation of Successful	ASBS	X	X					

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures	Other Quality	Reporting	Frograms
262			Excision of Image–Localized Breast Lesion: Image confirmation of lesion(s) targeted for image guided excisional biopsy or image guided partial mastectomy in patients with nonpalpable, image-detected breast lesion(s). Lesions may include: microcalcifications, mammographic or sonographic mass or architectural distortion, focal suspicious abnormalities on magnetic resonance imaging (MRI) or other breast imaging amenable to localization such as positron emission tomography (PET) mammography, or a biopsy marker demarcating site of confirmed pathology as established by previous core biopsy. This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).									
N/A/ 263		Effective Clinical Care	Preoperative Diagnosis of Breast Cancer: The percent of patients undergoing breast cancer operations	ASBS	X	X						

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality	Reporting Programs
			who obtained the diagnosis of breast cancer preoperatively by a minimally invasive biopsy method								
			This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).								
N/A/ 264		Effective Clinical Care	Sentinel Lymph Node Biopsy for Invasive Breast Cancer: The percentage of clinically node negative (clinical stage T1N0M0 or T2N0M0) breast cancer patients who undergo a sentinel lymph node (SLN) procedure	ASBS		X					
			This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).								
0645/ 265		Communication and Care Coordination	Biopsy Follow-Up: Percentage of new patients whose biopsy results have been reviewed and communicated to the primary care/referring physician and patient by the performing physician	AAD		X					
			This measure was finalized for								

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web	Measures	Groups Other Onelity	Cinet Quanty Renorting	Programs
			inclusion in 2014 PQRS in the CY 2013									
			PFS Final Rule (see Table 95 at 77 FR 69215).									
N/A/		Effective Clinical Care	Epilepsy: Seizure Type(s) and	AAN	X	X						
266		Effective Clinical Care	Current Seizure Frequency(ies): Percentage of patient visits with a diagnosis of epilepsy who had the type(s) of seizure(s) and current seizure frequency(ies) for each seizure type documented in the medical record This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).	AAN	A	A						
N/A/ 267		Effective Clinical Care	Epilepsy: Documentation of Etiology of Epilepsy or Epilepsy Syndrome: All visits for patients with a diagnosis of epilepsy who had their etiology of epilepsy or with epilepsy syndrome(s) reviewed and documented if known, or documented as unknown or cryptogenic This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR	AAN	X	X						

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure	Claims	Registry	EHR	GPRO (Web Interface)*	Measures	Groups	Other Quanty	Keporting Programs
			69215).									
N/A/ 268		Effective Clinical Care	Epilepsy: Counseling for Women of Childbearing Potential with Epilepsy: All female patients of childbearing potential (12-44 years old) diagnosed with epilepsy who were counseled about epilepsy and how its treatment may affect contraception and pregnancy at least once a year This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR	AAN	X	X						
N/A/		Effective Clinical Care	69215). Inflammatory Bowel Disease (IBD):	AGA					X			
269			Type, Anatomic Location and Activity All Documented: Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease who have documented the disease type, anatomic location and activity, at least once during the reporting period									
			This measure was finalized for inclusion in 2014 PQRS in the CY 2013									

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web	Measures	Groups	Other Quality	Reporting Programs
			PFS Final Rule (see Table 95 at 77 FR 69215).									
N/A/ 270		Effective Clinical Care	Inflammatory Bowel Disease (IBD): Preventive Care: Corticosteroid Sparing Therapy: Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease who have been managed by corticosteroids greater than or equal to 10 mg/day for 60 or greater consecutive days that have been prescribed corticosteroid sparing therapy in the last reporting year This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).	AGA					X			
N/A/ 271		Effective Clinical Care	Inflammatory Bowel Disease (IBD): Preventive Care: Corticosteroid Related Iatrogenic Injury – Bone Loss Assessment: Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease who have received dose of	AGA					X			

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting	Reporting Programs
			corticosteroids greater than or equal to 10 mg/day for 60 or greater consecutive days and were assessed for risk of bone loss once per the reporting year This measure was finalized for inclusion in 2014 PQRS in the CY 2013								
27/11/			PFS Final Rule (see Table 95 at 77 FR 69215).								
N/A/ 272		Effective Clinical Care	Inflammatory Bowel Disease (IBD): Preventive Care: Influenza Immunization: Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease for whom influenza immunization was recommended, administered or previously received during the reporting year This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).	AGA					X		
N/A/ 273		Effective Clinical Care	Inflammatory Bowel Disease (IBD): Preventive Care: Pneumococcal Immunization: Percentage of patients	AGA					X		

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality	Reporting Programs
			aged 18 years and older with a diagnosis of inflammatory bowel disease that had pneumococcal vaccination administered or previously received								
			This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).								
N/A/ 274		Effective Clinical Care	Inflammatory Bowel Disease (IBD): Testing for Latent Tuberculosis (TB) Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy: Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease for whom a tuberculosis (TB) screening was performed and results interpreted within 6 months prior to receiving a first course of anti-TNF (tumor necrosis factor) therapy This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).	AGA					X		

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality	Reporting Programs
N/A/ 275		Effective Clinical Care	Inflammatory Bowel Disease (IBD): Assessment of Hepatitis B Virus (HBV) Status Before Initiating Anti- TNF (Tumor Necrosis Factor) Therapy: Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease who had Hepatitis B Virus (HBV) status assessed and results interpreted within 1 year prior to receiving a first course of anti-TNF (tumor necrosis factor) therapy This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).	AGA					X		
N/A/ 276		Effective Clinical Care	Sleep Apnea: Assessment of Sleep Symptoms: Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive sleep apnea that includes documentation of an assessment of sleep symptoms, including presence or absence of snoring and daytime sleepiness	AMA- PCPI/ NCQA					X		

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures	Other Quality	Reporting Programs
			This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).								
N/A/ 277		Effective Clinical Care	Sleep Apnea: Severity Assessment at Initial Diagnosis: Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI) or a respiratory disturbance index (RDI) measured at the time of initial diagnosis This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).	AMA- PCPI/ NCQA					X		
N/A/ 278		Effective Clinical Care	Sleep Apnea: Positive Airway Pressure Therapy Prescribed: Percentage of patients aged 18 years and older with a diagnosis of moderate or severe obstructive sleep apnea who were prescribed positive airway pressure therapy This measure was finalized for	AMA- PCPI/ NCQA					X		

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality	Reporting Programs
			inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).								
N/A/ 279		Effective Clinical Care	Sleep Apnea: Assessment of Adherence to Positive Airway Pressure Therapy: Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive sleep apnea who were prescribed positive airway pressure therapy who had documentation that adherence to positive airway pressure therapy was objectively measured This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).	AMA- PCPI/ NCQA					X		
N/A/ 280		Communication and Care Coordination	Dementia: Staging of Dementia: Percentage of patients, regardless of age, with a diagnosis of dementia whose severity of dementia was classified as mild, moderate or severe at least once within a 12 month period This measure was finalized for	AMA-PCPI					X		

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting	Programs
			inclusion in 2014 PQRS in the CY 2013								
			PFS Final Rule (see Table 95 at 77 FR 69215).								
N/A/	149v2	Effective Clinical Care	Dementia: Cognitive Assessment:	AMA-PCPI			X		X	MU2	_
281	11712	Encerve Chinear Care	Percentage of patients, regardless of	7111777777			71		71	WICZ	
			age, with a diagnosis of dementia for								
			whom an assessment of cognition is								
			performed and the results reviewed at								
			least once within a 12 month period								
			*The EHR-based reporting option is								
			available for reporting this measure								
			beginning in 2014.*								
			In an effort to align with the EHR								
			Incentive Program, this measure will be								
			reportable via EHR beginning in 2014.								
			The alignment of measures contained								
			within multiple CMS reporting								
			programs eases the burden of reporting								
			and encourages eligible professionals to								
			submit quality clinical data on care								
			provided for Medicare beneficiaries. Alignment also promotes a robust data								
			source and consistency in analysis,								
			which supports other quality programs								

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
			within CMS. For these reasons, we are finalizing the addition of the EHR-based reporting option for this measure beginning in 2014.							
N/A/ 282		Effective Clinical Care	Assessment: Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of patient's functional status is performed and the results reviewed at least once within a 12 month period This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).	AMA-PCPI					X	
N/A/ 283		Effective Clinical Care	Dementia: Neuropsychiatric Symptom Assessment: Percentage of patients, regardless of age, with a diagnosis of dementia and for whom an assessment of patient's neuropsychiatric symptoms is performed and results reviewed at least once in a 12 month period This measure was finalized for	AMA-PCPI					X	

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting	Programs
			inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).								
N/A/ 284		Effective Clinical Care	Dementia: Management of Neuropsychiatric Symptoms: Percentage of patients, regardless of age, with a diagnosis of dementia who have one or more neuropsychiatric symptoms who received or were recommended to receive an intervention for neuropsychiatric symptoms within a 12 month period This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).	AMA-PCPI					X		
N/A/ 285		Effective Clinical Care	Dementia: Screening for Depressive Symptoms: Percentage of patients, regardless of age, with a diagnosis of dementia who were screened for depressive symptoms within a 12 month period This measure was finalized for inclusion in 2014 PQRS in the CY 2013	AMA-PCPI					X		

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures	Other Quality	Reporting Programs
			PFS Final Rule (see Table 95 at 77 FR 69215).								
N/A/ 286		Patient Safety	Dementia: Counseling Regarding Safety Concerns: Percentage of patients, regardless of age, with a diagnosis of dementia or their caregiver(s) who were counseled or referred for counseling regarding safety concerns within a 12 month period This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).	AMA-PCPI					X		
N/A/ 287		Effective Clinical Care	Dementia: Counseling Regarding Risks of Driving: Percentage of patients, regardless of age, with a diagnosis of dementia or their caregiver(s) who were counseled regarding the risks of driving and the alternatives to driving at least once within a 12 month period This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR	AMA-PCPI					X		

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures	Other Quality	Reporting Programs
			69215).								
N/A/ 288		Effective Clinical Care	Dementia: Caregiver Education and Support: Percentage of patients, regardless of age, with a diagnosis of dementia whose caregiver(s) were provided with education on dementia disease management and health behavior AND referred to additional sources for support within a 12 month period	AMA-PCPI					X		
			This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).								
N/A/		Effective Clinical Care	Parkinson's Disease: Annual	AAN					X		
289			Parkinson's Disease Diagnosis Review: All patients with a diagnosis of Parkinson's disease who had an annual assessment including a review of current medications (e.g., medications than can produce Parkinson-like signs or symptoms) and a review for the presence of atypical features (e.g., falls at presentation and early in the disease course, poor								

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality	Reporting Programs
			response to levodopa, symmetry at onset, rapid progression [to Hoehn and Yahr stage 3 in 3 years], lack of tremor or dysautonomia) at least annually This measure was finalized for inclusion in 2014 PQRS in the CY 2013								
			PFS Final Rule (see Table 95 at 77 FR 69215).								
N/A/ 290		Effective Clinical Care	Parkinson's Disease: Psychiatric Disorders or Disturbances Assessment: All patients with a diagnosis of Parkinson's disease who were assessed for psychiatric disorders or disturbances (e.g., psychosis, depression, anxiety disorder, apathy, or impulse control disorder) at least annually This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).	AAN					X		
N/A/ 291		Effective Clinical Care	Parkinson's Disease: Cognitive Impairment or Dysfunction Assessment: All patients with a	AAN					X		

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures	Other Quality	Reporting Programs
			diagnosis of Parkinson's disease who were assessed for cognitive impairment or dysfunction at least annually								
			This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).								
N/A/ 292		Effective Clinical Care	Parkinson's Disease: Querying about Sleep Disturbances: All patients with a diagnosis of Parkinson's disease (or caregivers, as appropriate) who were queried about sleep disturbances at least annually	AAN					X		
			This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).								
N/A/ 293		Effective Clinical Care	Parkinson's Disease: Rehabilitative Therapy Options: All patients with a diagnosis of Parkinson's disease (or caregiver(s), as appropriate) who had rehabilitative therapy options (e.g., physical, occupational, or speech therapy) discussed at least annually	AAN					X		

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality	Keporting Programs
			This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).								
N/A/ 294		Effective Clinical Care	Parkinson's Disease: Parkinson's Disease Medical and Surgical Treatment Options Reviewed: All patients with a diagnosis of Parkinson's disease (or caregiver(s), as appropriate who had the Parkinson's disease treatment options (e.g., non- pharmacological treatment, pharmacological treatment, or surgical treatment) reviewed at least once annually This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).	AAN					X		
N/A/ 295		Effective Clinical Care	Hypertension: Use of Aspirin or Other Antithrombotic Therapy: Percentage of patients aged 30 through 90 years old with a diagnosis of hypertension and are eligible for aspirin	ABIM					X		

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality	Reporting Programs
			or other antithrombotic therapy who were prescribed aspirin or other antithrombotic therapy								
			This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).								
N/A/ 296		Effective Clinical Care	Hypertension: Complete Lipid Profile: Percentage of patients aged 18 through 90 years old with a diagnosis of hypertension who received a complete lipid profile within 60 months	ABIM					X		
			This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).								
N/A/ 297		Effective Clinical Care	Hypertension: Urine Protein Test: Percentage of patients aged 18 through 90 years old with a diagnosis of hypertension who either have chronic kidney disease diagnosis documented or had a urine protein test done within 36 months	ABIM					X		

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality	reporting Programs
			This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).								
N/A/ 298		Effective Clinical Care	Hypertension: Annual Serum Creatinine Test: Percentage of patients aged 18 through 90 years old with a diagnosis of hypertension who had a serum creatinine test done within 12 months This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).	ABIM					X		
N/A/ 299		Effective Clinical Care	Hypertension: Diabetes Mellitus Screening Test: Percentage of patients aged 18 through 90 years old with a diagnosis of hypertension who had a diabetes screening test within 36 months This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).	ABIM					X		

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting	Programs
N/A/ 300		Effective Clinical Care	Hypertension: Blood Pressure Control: Percentage of patients aged 18 through 90 years old with a diagnosis of hypertension whose most recent blood pressure was under control (< 140/90 mmHg) This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).	ABIM					X		
N/A/ 301		Effective Clinical Care	Hypertension: Low Density Lipoprotein (LDL-C) Control: Percentage of patients aged 18 through 90 years old with a diagnosis of hypertension whose most recent LDL cholesterol level was under control (at goal) This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).	ABIM					X		
N/A/ 302		Effective Clinical Care	Hypertension: Dietary and Physical Activity Modifications Appropriately Prescribed: Percentage of patients	ABIM					X		

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting
			aged 18 through 90 years old with a diagnosis of hypertension who received dietary and physical activity counseling at least once within 12 months This measure was finalized for inclusion in 2014 PQRS in the CY 2013							
			PFS Final Rule (see Table 95 at 77 FR 69215).							
N/A/ 303		Effective Clinical Care	Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery: Percentage of patients aged 18 years and older in sample who had cataract surgery and had improvement in visual function achieved within 90 days following the cataract surgery, based on completing a pre-operative and post- operative visual function survey This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).	AAO		X			X	
N/A/		Person and Caregiver-	Cataracts: Patient Satisfaction within	AAO		X			X	
304		Centered Experience	90 Days Following Cataract Surgery:							

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality	Reporting Programs
		and Outcomes	Percentage of patients aged 18 years and older in sample who had cataract surgery and were satisfied with their care within 90 days following the cataract surgery, based on completion of the Consumer Assessment of Healthcare Providers and Systems Surgical Care Survey								
			This measure was finalized for								
			inclusion in 2014 PQRS in the CY 2013								
			PFS Final Rule (see Table 95 at 77 FR 69215).								
0004/305	137v2	Effective Clinical Care	Initiation and Engagement of Alcohol and Other Drug Dependence Treatment: Percentage of patients 13 years of age and older with a new episode of alcohol and other drug (AOD) dependence who received the following. Two rates are reported. a. Percentage of patients who initiated treatment within 14 days of the diagnosis. b. Percentage of patients who initiated treatment and who had two or more additional services with an AOD diagnosis within 30 days of the initiation visit.	NCQA			X			M	U2

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality	Reporting Programs
			This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).								
0032/ 309	124v2	Effective Clinical Care	Cervical Cancer Screening: Percentage of women 21-64 years of age, who received one or more Pap tests to screen for cervical cancer. This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).	NCQA			X			MU	J2
0033/310	153v2	Community/ Population Health	Chlamydia Screening for Women: Percentage of women 16-24 years of age who were identified as sexually active and who had at least one test for chlamydia during the measurement period This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).	NCQA			X			MU	J2
0036/ 311	126v2	Effective Clinical Care	Use of Appropriate Medications for Asthma: Percentage of patients 5-64 years of age who were identified as having persistent asthma and were appropriately	NCQA			X			MU	J2

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
			prescribed medication during the measurement period This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).							
0052/ 312	166v3	Efficiency and Cost Reduction	Use of Imaging Studies for Low Back Pain: Percentage of patients 18-50 years of age with a diagnosis of low back pain who did not have an imaging study (plain X-ray, MRI, CT scan) within 28 days of the diagnosis. This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).	NCQA			X			MU2
N/A/ 316	61v3 and 64v3	Effective Clinical Care	Preventive Care and Screening: Cholesterol – Fasting Low Density Lipoprotein (LDL-C) Test Performed AND Risk-Stratified Fasting LDL-C: Percentage of patients aged 20 through 79 years whose risk factors* have been assessed and a fasting LDL test has been performed AND percentage of patients aged 20 through 79 years who had a fasting LDL-C test performed and	CMS			X			MU2 Million Hearts

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
			whose risk-stratified fasting LDL-C is at or below the recommended LDL-C goal. *There are three criteria for this measure based on the patient's risk category. 1. Highest Level of Risk: Coronary Heart Disease (CHD) or CHD Risk Equivalent OR 10-Year Framingham Risk >20% 2. Moderate Level of Risk: Multiple (2+) Risk Factors OR 10-Year Framingham Risk 10-20% 3. Lowest Level of Risk: 0 or 1 Risk Factor OR 10-Year Framingham Risk <10% This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).							
N/A/ 317	22v2	Community/ Population Health	Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented: Percentage of patients aged 18 years and older seen during the reporting	CMS	X	X	X	X	X	MU2 ACO Million Hearts

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality	Reporting Programs
			period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated								
			This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).								
0101/318	139v2	Patient Safety	Falls: Screening for Future Fall Risk: Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period. *The EHR-based reporting option is available for reporting this measure beginning in 2014.* In an effort to align with the EHR Incentive Program, this measure will be reportable via EHR beginning in 2014. The alignment of measures contained within multiple CMS reporting programs eases the burden of reporting and encourages eligible professionals to	NCQA			X	X		MU AC	

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting	Programs
0729/319		Effective Clinical Care	submit quality clinical data on care provided for Medicare beneficiaries. Alignment also promotes a robust data source and consistency in analysis, which supports other quality programs within CMS. For these reasons, we are finalizing the addition of the EHR-based reporting option for this measure beginning in 2014. Diabetes Composite: Optimal Diabetes Care: Patients ages 18 through 75 with a diagnosis of diabetes, who meet all the numerator targets of this composite measure: • A1c < 8.0%, • LDL < 100 mg/dL, • blood pressure < 140/90 mmHg, • tobacco non-user and	MNCM				X		ACO	
			• for patients with a diagnosis of ischemic vascular disease daily aspirin use unless contraindicated This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).								
0658/ 320		Communication and Care Coordination	Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for	AMA-PCPI	X	X					

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Renorting	Programs
			Normal Colonoscopy in Average Risk Patients: Percentage of patients aged 50 years and older receiving a screening colonoscopy without biopsy or polypectomy who had a recommended follow-up interval of at least 10 years for repeat colonoscopy documented in their colonoscopy report This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).								
0005& 0006/ 321		Communication and Care Coordination	 CG-CAHPS Clinician/Group Survey Getting timely care, appointments, and information; How well providers Communicate; Patient's Rating of Provider; Access to Specialists; Health Promotion & Education; Shared Decision Making; Health Status/Functional	ASPE				X		ACC	O

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality	Reporting Programs
			 Helping Your to Take Medication as Directed; and Stewardship of Patient Resources This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215). 								
0670/322		Efficiency and Cost Reduction	Appropriate Use Criteria: Preoperative Evaluation in Low-Risk Surgery Patients: Percentage of stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echocardiogram (ECHO), cardiac computed tomography angiography (CCTA), or cardiac magnetic resonance (CMR) performed in low risk surgery patients 18 years or older for preoperative evaluation during the 12- month reporting period This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR	ACC		X					

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure	Claims	Registry	EHR	GPRO (Web	Measures	Groups	Other Quality	Reporting Programs	I i ugi ams
			69215).										
0671/323		Efficiency and Cost Reduction	Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Routine Testing After Percutaneous Coronary Intervention (PCI): Percentage of all stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echocardiogram (ECHO), cardiac computed tomography angiography (CCTA), and cardiovascular magnetic resonance (CMR) performed in patients aged 18 years and older routinely after percutaneous coronary intervention (PCI), with reference to timing of test after PCI and symptom status This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule	ACC		X							
0672/		Efficiency and Cost	(see Table 95 at 77 FR 69215). Cardiac Stress Imaging Not Meeting	ACC		X							-
324		Reduction Reduction	Appropriate Use Criteria: Testing in										
			Asymptomatic, Low-Risk Patients: Percentage of all stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echocardiogram (ECHO), cardiac computed tomography angiography (CCTA), and cardiovascular magnetic resonance (CMR) performed in asymptomatic,										

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure	Claims	Registry	EHR	GPRO (Web Interface)*	Measures	Other Quality	Reporting Programs
			low coronary heart disease (CHD) risk								
			patients 18 years and older for initial								
			detection and risk assessment								
			This measure was finalized for								
			inclusion in 2014 PQRS in the CY 2013								
			PFS Final Rule (see Table 95 at 77 FR								
			69215).								
N/A/		Effective Clinical Care	Adult Major Depressive Disorder	AMA-PCPI		X					
325			(MDD): Coordination of Care of								
			Patients with Specific Comorbid								
			Conditions: Percentage of medical								
			records of patients aged 18 years and								
			older with a diagnosis of major								
			depressive disorder (MDD) and a								
			specific diagnosed comorbid condition								
			(diabetes, coronary artery disease,								
			ischemic stroke, intracranial								
			hemorrhage, chronic kidney disease								
			[stages 4 or 5], End Stage Renal								
			Disease [ESRD] or congestive heart								
			failure) being treated by another								
			clinician with communication to the								
			clinician treating the comorbid								
			condition								

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web	Measures	Other Quality	Reporting	Programs
			This measure was finalized for									
			inclusion in 2014 PQRS in the CY 2013									
			PFS Final Rule (see Table 95 at 77 FR 69215).									
1525/		Patient Safety	Atrial Fibrillation and Atrial Flutter:	AMA-PCPI/	X	X						
326			Chronic Anticoagulation Therapy:	ACCF/AHA								
			Percentage of patients aged 18 years									
			and older with a diagnosis of									
			nonvalvular atrial fibrillation (AF) or									
			atrial flutter whose assessment of the									
			specified thromboembolic risk factors									
			indicate one or more high-risk factors									
			or more than one moderate risk factor,									
			as determined by CHADS2 risk									
			stratification, who are prescribed									
			warfarin OR another oral anticoagulant									
			drug that is FDA approved for the									
			prevention of thromboembolism									
			This measure was finalized for									
			inclusion in 2014 PQRS in the CY 2013									
			PFS Final Rule (see Table 95 at 77 FR									
			69215).									
N/A/		Effective Clinical Care	Pediatric Kidney Disease: Adequacy	AMA	X	X						
327			of Volume Management: Percentage									
			of calendar months within a 12-month									

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality	Reporting Programs
			period during which patients aged 17 years and younger with a diagnosis of End Stage Renal Disease (ESRD) undergoing maintenance hemodialysis in an outpatient dialysis facility have an assessment of the adequacy of volume management from a nephrologist This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR 69215).								
1667/ 328		Effective Clinical Care	Pediatric Kidney Disease: ESRD Patients Receiving Dialysis: Hemoglobin Level < 10 g/dL: Percentage of calendar months within a 12-month period during which patients aged 17 years and younger with a diagnosis of End Stage Renal Disease (ESRD) receiving hemodialysis or peritoneal dialysis have a hemoglobin level < 10 g/dL This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 95 at 77 FR	AMA-PCPI	X	X					

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure	Claims	Registry	EHR	GPRO (Web Interface)*	Measures	Other Quality	Reporting Programs
			69215).								
N/A/N/A‡		Effective Clinical Care	Adult Kidney Disease: Catheter Use	AMA-PCPI		X					
			at Initiation of Hemodialysis:								
			Percentage of patients aged 18 years								
			and older with a diagnosis of End Stage								
			Renal Disease (ESRD) who initiate								
			maintenance hemodialysis during the								
			measurement period, whose mode of								
			vascular access is a catheter at the time								
			maintenance hemodialysis is initiated								
			Several commenters supported the								
			inclusion of this measure, stating								
			catheter use is the primary contributing								
			factor to bloodstream infections in								
			hemodialysis patients. We appreciate								
			the commenters' feedback and believe								
			this measure will help deter the use of								
			catheters for hemodialysis patients.								
			Additionally, this measure expands								
			upon the care that is represented in								
			adult kidney disease patient population.								
			It allows eligible professionals								
			providing care for these patients a								
			greater variety of measures to report.								
			For the reasons previously stated, we								

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web	Measures	Other Quality	Reporting	Programs
			finalizing this individual measure for									
			reporting beginning in 2014.									
N/A/N/A‡		Effective Clinical Care	Adult Kidney Disease: Catheter Use	AMA-PCPI		X						
			for Greater Than or Equal to 90									
			Days: Percentage of patients aged 18									
			years and older with a diagnosis of End									
			Stage Renal Disease (ESRD) receiving									
			maintenance hemodialysis for greater									
			than or equal to 90 days whose mode of									
			vascular access is a catheter									
			Several commenters supported the									
			inclusion of this measure, stating									
			physician referrals for appropriate									
			vascular access placement in patients									
			who will soon need dialysis and who									
			are already on dialysis, are important to									
			reducing the use of catheters in									
			hemodialysis patients. We agree with									
			the commenters' feedback this measure									
			expands upon the care that is									
			represented in adult kidney disease									
			patient population. Additionally, it									
			allows eligible professionals providing									
			care for these patients a greater variety									
			of measures to report. For the reasons									

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure	Claims	Registry	EHR	GPRO (Web Interface)*	Measures	Other Quality	Reporting Programs
			previously stated, we finalizing this								
			individual measure for reporting								
27/1 27/1 1			beginning in 2014.						-		
N/A/N/A‡		Effective Clinical Care	Adult Sinusitis: Antibiotic Prescribed	AMA-PCPI		X					
			for Acute Sinusitis (Appropriate								
			Use): Percentage of patients, aged 18								
			years and older, with a diagnosis of								
			acute sinusitis who were prescribed an								
			antibiotic within 7 days of diagnosis or								
			within 10 days after onset of symptoms								
			Several commenters supported the								
			inclusion of this measure. One								
			commenter requested clarification as to								
			why this measure has been included for								
			registry-only reporting, despite requests								
			that it also be included for EHR-based								
			reporting. In an effort to streamline the								
			reporting options available under the								
			PQRS and to eliminate reporting								
			options that are not widely used, all								
			new measures incorporated in PQRS								
			are available via registry-only.								
			Additionally, for CY 2014, CMS was								
			unable to determine the feasibility of								
			incorporation of this measure for other								

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure	Claims	Registry	EHR	GPRO (Web	Measures	Groups	Other Quality	Reporting Programs
			reporting options; however, CMS									
			intends to continue working toward									
			complete alignment of measure									
			specifications across programs whenever possible and incorporation of									
			this measure for EHR-based reporting									
			1									
			may be considered in the future.									
			This measure represents a new medical									
			concept and fills a gap in care not									
			previously addressed by the PQRS. The									
			measure is reportable by Ear, Nose and									
			Throat (ENT) and other eligible									
			professionals within this specific scope									
			of practice that previously had a limited									
			number of measures available for									
			reporting within PQRS. For these									
			reasons, we are finalizing this measure									
			for registry-based reporting beginning									
			in 2014.									
N/A/N/A‡		Effective Clinical Care	Adult Sinusitis: Appropriate Choice	AMA-PCPI		X						
			of Antibiotic: Amoxicillin Prescribed									
			for Patients with Acute Bacterial									
			Sinusitis: Percentage of patients aged									
			18 years and older with a diagnosis of									
			acute bacterial sinusitis that were									

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures	Other Quality	Reporting Programs
			prescribed amoxicillin, without								
			clavulante, as a first line antibiotic at the time of diagnosis								
			Several commenters expressed general								
			support for the inclusion of this measure. One commenter requested								
			clarification as to why this measure has								
			been included for registry-only								
			reporting, despite requests that it also								
			be included for EHR-based reporting.								
			In an effort to streamline the reporting								
			options available under the PQRS and								
			to eliminate reporting options that are								
			not widely used, all new measures								
			incorporated in PQRS are available via registry-only. Additionally, for CY								
			2014, CMS was unable to determine the								
			feasibility of incorporation of this								
			measure for other reporting options;								
			however, CMS intends to continue								
			working toward complete alignment of								
			measure specifications across programs								
			whenever possible and incorporation of								
			this measure for EHR-based reporting								
			may be considered in the future.								

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality	Reporting Programs
			This measure represents a new medical concept and fills a gap in care not previously addressed by the PQRS. The measure is reportable by Ear, Nose and Throat (ENT) and other eligible professionals within this specific scope of practice that previously had a limited number of measures available for reporting within PQRS. For these reasons, we are finalizing this measure for registry-based reporting beginning in 2014.								
N/A/N/A‡		Efficiency and Cost Reduction	Adult Sinusitis: Computerized Tomography for Acute Sinusitis (Overuse): Percentage of patients aged 18 years and older with a diagnosis of acute sinusitis who had a computerized tomography (CT) scan of the paranasal sinuses ordered at the time of diagnosis or received within 28 days after date of diagnosis Several commenters supported the inclusion of this measure. One commenter requested clarification as to	AMA-PCPI		X					

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure	Claims	Registry	EHR	GPRO (Web	meriace)	Groups	Other Quality	Reporting	Programs
			why this measure has been included for										
			registry-only reporting, despite requests										
			that it also be included for EHR-based										
			reporting. In an effort to streamline the										
			reporting options available under the										
			PQRS and to eliminate reporting										
			options that are not widely used, all										
			new measures incorporated in PQRS										
			are available via registry-only.										
			Additionally, for CY 2014, CMS was										
			unable to determine the feasibility of										
			incorporation of this measure for other										
			reporting options; however, CMS										
			intends to continue working toward										
			complete alignment of measure										
			specifications across programs										
			whenever possible and incorporation of										
			this measure for EHR-based reporting										
			may be considered in the future.										
			This measure represents a new medical										
			concept and fills a gap in care not										
			previously addressed by the PQRS. The										
			measure is reportable by Ear, Nose and										
			Throat (ENT) and other eligible										

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure	Claims	Registry	EHR	GPRO (Web Interface)*	Measures	Other Quality	Reporting	Programs
			professionals within this specific scope of practice that previously had a limited number of measures available for reporting within PQRS. For these reasons, we are finalizing this measure for registry-based reporting beginning in 2014.									
N/A/N/A‡		Efficiency and Cost Reduction	Adult Sinusitis: More than One Computerized Tomography (CT) Scan Within 90 Days for Chronic Sinusitis (Overuse): Percentage of patients aged 18 years and older with a diagnosis of chronic sinusitis who had more than one CT scan of the paranasal sinuses ordered or received within 90 days after the date of diagnosis	AMA-PCPI		X						
			Several commenters expressed general support for the inclusion of this measure. One commenter requested clarification as to why this measure has been included for registry-only reporting, despite requests that it also be included for EHR-based reporting. In an effort to streamline the reporting options available under the PQRS and									

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures	Other Quality	Reporting Programs	1106141115
			to eliminate reporting options that are									
			not widely used, all new measures									
			incorporated in PQRS are available via registry-only.									
			Additionally, for CY 2014, CMS was									
			unable to determine the feasibility of									
			incorporation of this measure for other									
			reporting options; however, CMS									
			intends to continue working toward									
			complete alignment of measure									
			specifications across programs whenever possible and incorporation of									
			this measure for EHR-based reporting									
			may be considered in the future.									
			may be considered in the future.									
			This measure represents a new medical									
			concept and fills a gap in care not									
			previously addressed by the PQRS. The									
			measure is reportable by Ear, Nose and									
			Throat (ENT) and other eligible									
			professionals within this specific scope									
			of practice that previously had a limited									
			number of measures available for									
			reporting within PQRS. For these									
			reasons, we are finalizing this measure									

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure	Claims	Registry	EHR	GPRO (Web Interface)*	Measures	Groups Other Onality	Reporting	Programs
			for registry-based reporting beginning in 2014.									
N/A/N/A‡		Patient Safety	Maternity Care: Elective Delivery or Early Induction Without Medical Indication at ≥ 37 and < 39 Weeks: Percentage of patients, regardless of age, who gave birth during a 12-month period who delivered a live singleton at ≥ 37 and < 39 weeks of gestation completed who had elective deliveries or early inductions without medical indication One commenter expressed general support for the inclusion of this measure and proposed it be adopted for EHR reporting in the future. We appreciate the commenter's support of this measure. For CY 2014, CMS was unable to determine the feasibility of incorporation of this measure for other reporting options; however, CMS intends to continue working toward complete alignment of measure specifications across programs whenever possible and incorporation of	AMA-PCPI		X						

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality	Reporting Programs
			this measure for EHR-based reporting may be considered in the future. This measure represents a new medical concept within PQRS, reportable by								
			Obstetrics/Gynecologist and other eligible professionals within this specific scope of practice who previously had a limited number of measures available for reporting. For these reasons, we are finalizing this measure for registry-based reporting beginning in 2014.								
N/A/N/A‡		Communication and Care Coordination	Maternity Care: Post-Partum Follow-Up and Care Coordination: Percentage of patients, regardless of age, who gave birth during a 12-month period who were seen for post-partum care within 8 weeks of giving birth who received a breast feeding evaluation and education, post-partum depression screening, post-partum glucose screening for gestational diabetes patients, and family and contraceptive planning	AMA-PCPI		X					

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web	Measures	Groups Other Onality	Renorting	Programs
			One commenter expressed general									
			support for the inclusion of this									
			measure and proposed it be adopted for									
			EHR reporting in the future. We									
			appreciate the commenter's support of									
			this measure. For CY 2014, CMS was									
			unable to determine the feasibility of									
			incorporation of this measure for other									
			reporting options; however, CMS									
			intends to continue working toward									
			complete alignment of measure									
			specifications across programs whenever possible and incorporation of									
			this measure for EHR-based reporting									
			may be considered in the future.									
			may be considered in the future.									
			This measure represents a new medical									
			concept within PQRS, reportable by									
			Obstetrics/Gynecologist and other									
			eligible professionals within this									
			specific scope of practice who									
			previously had a limited number of									
			measures available for reporting. For									
			these reasons, we are finalizing this									
			measure for registry-based reporting									
			beginning in 2014.									

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure	Claims	Registry	EHR	GPRO (Web	Measures	Groups	Other Quality	Keporung Programs
N/A/N/A‡		Effective Clinical Care	Tuberculosis Prevention for Psoriasis	AAD		X						
			and Psoriatic Arthritis Patients on a									
			Biological Immune Response									
			Modifier: Percentage of patients whose									
			providers are ensuring active									
			tuberculosis prevention either through									
			yearly negative standard tuberculosis									
			screening tests or are reviewing the									
			patient's history to determine if they									
			have had appropriate management for a recent or prior positive test									
			recent of prior positive test									
			One commenter expressed general									
			support for the inclusion of this									
			measure. We appreciate the									
			commenters' feedback.									
			Psoriasis is a new medical concept for									
			reporting within PQRS and fills a gap									
			in care not previously addressed by the									
			PQRS. This measure would provide									
			Dermatology and other related eligible									
			professionals an additional measure to									
			report within PQRS. This measure									
			could also be reported by other									
			professionals that treat joint care, such									

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality	Reporting Programs
			as Family Practice and Rheumatologists. For these reasons, we are finalizing this measure for reporting beginning in 2014.								
2082/N/A‡		Effective Clinical Care	HIV Viral Load Suppression: The percentage of patients, regardless of age, with a diagnosis of HIV with a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year	HRSA		X			X		
			This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule.								
2083/N/A‡		Effective Clinical Care	Prescription of HIV Antiretroviral Therapy: Percentage of patients, regardless of age, with a diagnosis of HIV prescribed antiretroviral therapy for the treatment of HIV infection during the measurement year	HRSA		X			X		
			This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule.								
N/A/ 2079‡		Efficiency and Cost Reduction	HIV Medical Visit Frequency: Percentage of patients, regardless of age	HRSA					X		

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality	Reporting Programs
			with a diagnosis of HIV who had at least one medical visit in each 6 month period of the 24 month measurement period, with a minimum of 60 days between medical visits This measure was finalized for								
			inclusion in 2014 PQRS in the CY 2013 PFS Final Rule.								
N/A/ 2080‡		Efficiency and Cost Reduction	Gap in HIV Medical Visits: Percentage of patients, regardless of age, with a diagnosis of HIV who did not have a medical visit in the last 6 months	HRSA					X		
			This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule.								
0209/N/A‡		Person and Caregiver- Centered Experience and Outcomes	Pain Brought Under Control Within 48 Hours: Patients aged 18 and older who report being uncomfortable because of pain at the initial assessment (after admission to palliative care services) who report pain was brought to a comfortable level within 48 hours	NHPCO		X					

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure	Claims	Registry	EHR	GPRO (Web Interface)*	Measures	Other Quality	Reporting	Programs
			One commenter expressed general									
			support for the inclusion of this									
			measure. We appreciate the									
			commenter's support.									
			Previously, there were no measures within the PQRS that addressed care for patients being managed by palliative care or eligible professionals that would provide these services to patients. Pain management for patients receiving palliative care will provide beneficial									
			data for this medical concept. For these									
			reasons, we are finalizing this measure									
			for inclusion in PQRS beginning in									
			2014.									
N/A/N/A‡		Effective Clinical Care	Screening Colonoscopy Adenoma	ACG/		X						
			Detection Rate Measure: The	ASGE								
			percentage of patients age 50 years or									
			older with at least one adenoma or other									
			colorectal cancer precursor or colorectal									
			cancer detected during screening colonoscopy									
			One commenter agreed with CMS that									
			this measure, along with other existing									

PQRS colonoscopy measures, is vital to improving patient outcomes. Another commenter supported the inclusion of this measure but was concerned that it was proposed for registry-only reporting. In an effort to streamline the reporting options available under the PQRS and to eliminate reporting options that are not widely used, all new measures incorporated in PQRS are available via registry-only. Additionally, for CY 2014, CMS was unable to determine the feasibility of incorporation of this measure for other reporting options; however, CMS intends to continue working toward.	NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure	Claims	Registry	EHR	GPRO (Web	Interface)" Measures	Groups	Other Quality	Reporting Programs	I IUgi ams
complete alignment of measure specifications across programs whenever possible and incorporation of this measure in other PQRS reporting options may considered in the future. This measure addresses a broad patient				improving patient outcomes. Another commenter supported the inclusion of this measure but was concerned that it was proposed for registry-only reporting. In an effort to streamline the reporting options available under the PQRS and to eliminate reporting options that are not widely used, all new measures incorporated in PQRS are available via registry-only. Additionally, for CY 2014, CMS was unable to determine the feasibility of incorporation of this measure for other reporting options; however, CMS intends to continue working toward complete alignment of measure specifications across programs whenever possible and incorporation of this measure in other PQRS reporting options may considered in the future.										

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality	Reporting Programs
			population for screening and detection								
			of colorectal cancer and is medically								
			significant in the measurement of								
			utilizing preventive healthcare								
			services For this reason, we are								
			finalizing this individual measure for								
			registry reporting beginning in 2014.								
N/A/N/A‡		Effective Clinical Care	Rate of Carotid Artery Stenting	SVS		X					
			(CAS) for Asymptomatic Patients,								
			Without Major Complications								
			(Discharged to Home by Post-								
			Operative Day #2): Percent of								
			asymptomatic patients undergoing CAS								
			who are discharged to home no later								
			than post-operative day #2								
			Several commenters expressed general								
			support for the inclusion of this								
			measure in PQRS beginning in 2014.								
			We appreciate the commenters' support								
			Additionally, this measure provides								
			opportunity for Vascular Surgical								
			eligible professionals to report a greater								
			number of measures. CMS' goal is to								
			provide ample reporting opportunities								

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Renorting	Programs
			to eligible professionals, especially those who are unable to report other broadly applicable measures. For this reason, we are finalizing this measure for inclusion in PQRS beginning in 2014.								
N/A/N/A‡		Effective Clinical Care	Rate of Postoperative Stroke or Death in Asymptomatic Patients Undergoing Carotid Artery Stenting (CAS): Percent of asymptomatic patients undergoing CAS who experience stroke or death following surgery while in the hospital Several commenters expressed general support for the inclusion of this measure in 2014 PQRS. One commenter supported the inclusion of this measure but was concerned that it was proposed for registry-only reporting. In an effort to streamline the reporting options available under the PQRS and to eliminate reporting options that are not widely used, all new measures incorporated in PQRS are available via registry-only.	SVS		X					

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web	Intertace)* Measures	Groups	Other Quality	Reporting	Programs
			Additionally, for CY 2014, CMS was unable to determine the feasibility of incorporation of this measure for other reporting options; however, CMS intends to continue working toward complete alignment of measure specifications across programs whenever possible and incorporation of this measure in other PQRS reporting options may considered in the future. This measure provides opportunity for Vascular Surgical eligible professionals to report a greater number of measures. CMS' goal is to provide ample reporting opportunities to eligible professionals, especially those who are unable to report other broadly applicable measures. For this reason, we are finalizing this measure for inclusion in PQRS beginning in 2014.										
N/A/N/A‡		Effective Clinical Care	Rate of Postoperative Stroke or Death in Asymptomatic Patients undergoing Carotid Endarterectomy (CEA): Percent of	SVS		X							

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures	Groups Other Onality	Reporting	Programs
			asymptomatic patients undergoing CEA									
			who experience stroke or death									
			following surgery while in the hospital									
			Several commenters expressed general									
			support for the inclusion of this									
			measure in 2014 PQRS. One									
			commenter supported the inclusion of									
			this measure but was concerned that it									
			was proposed for registry-only									
			reporting. In an effort to streamline the									
			reporting options available under the									
			PQRS and to eliminate reporting									
			options that are not widely used, all									
			new measures incorporated in PQRS									
			are available via registry-only.									
			Additionally, for CY 2014, CMS was									
			unable to determine the feasibility of									
			incorporation of this measure for other									
			reporting options; however, CMS									
			intends to continue working toward									
			complete alignment of measure									
			specifications across programs									
			whenever possible and incorporation of									
			this measure in other PQRS reporting									

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality	Reporting Programs
			options may considered in the future. This measure provides opportunity for Vascular Surgical eligible professionals to report a greater number of measures. CMS' goal is to provide ample reporting opportunities to eligible professionals, especially those who are unable to report other broadly applicable measures. For this reason, we are finalizing this measure for inclusion in PQRS beginning in 2014.								
N/A/N/A‡		Effective Clinical Care	Rate of Endovascular Aneurysm Repair (EVAR) of Small or Moderate Non-Ruptured Abdominal Aortic Aneurysms (AAA) Who Die While in Hospital: Percent of patients undergoing endovascular repair of small or moderate abdominal aortic aneurysms (AAA) who die while in the hospital Several commenters expressed general support for the inclusion of this measure. We appreciate the commenters' feedback.	SVS		X					

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [*]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality	Reporting Programs
			This measure provides opportunity for Vascular Surgical eligible professionals to report a greater number of measures. CMS' goal is to provide ample reporting opportunities to eligible professionals, especially those who are unable to report other broadly applicable measures. For this reason, we are finalizing this measure for inclusion in PQRS beginning in 2014.								
N/A/N/A‡		Effective Clinical Care	HRS-3: Implantable Cardioverter- Defibrillator (ICD) Complications Rate: Patients with physician-specific risk-standardized rates of procedural complications following the first time implantation of an ICD Several commenters supported the inclusion of this measure in 2014 PQRS as it has the potential to significantly improve the quality of care delivered to patients with advanced heart disease. One commenter also expressed support for including this measure for registry-based reporting, stating the risk	HRS		X					

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures	Groups Other Onelity	Other Quanty	reporting Programs
			adjustment in this measure includes a number of data elements that could not be found in claims data. We appreciate the commenters' support.									
			This measure provides opportunity for Electrophysiologists and other eligible professionals within this scope of practice to report a greater number of measures. CMS' goal is to provide ample reporting opportunities to eligible professionals, especially those who may be unable to report other broadly applicable measures. For this reason, we are finalizing this measure for inclusion in PQRS beginning in 2014.									
N/A/N/A‡		Effective Clinical Care	Optimal Vascular Composite: Percent of patients aged 18 to 75 with ischemic vascular disease (IVD) who have optimally managed modifiable risk factors demonstrated by meeting all of the numerator targets of this patient level all-or-none composite measure: LDL less than 100, blood pressure less than 140/90, tobacco-free status, and	MNCM		X						

National Quality Strategy Domain	Measure Title and Description [*]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures	Groups	Other Quality Renorting	Programs
	daily aspirin use									
	One commenter provided general support for this measure but opposed its use due to its target population and emphasis on numerical value targets as numerical targets as they believe numerical targets provide an incentive to treat tests rather than symptoms. We respectfully disagree, as this composite encompasses measurements that address risk factors for the specific patient population diagnosed with vascular disease. Addressing risk factors with treatment such as antiplatelet therapy and assessing blood pressure, lipid control and smoking within this patient population are common annual assessments and treatment for patients diagnosed with vascular disease. Management of blood pressure and lipids and encouraging patients to avoid smoking and maintain an antiplatelet treatment is beneficial for this patient population. Additionally it is reportable by a									
		One commenter provided general support for this measure but opposed its use due to its target population and emphasis on numerical value targets as numerical targets as they believe numerical targets provide an incentive to treat tests rather than symptoms. We respectfully disagree, as this composite encompasses measurements that address risk factors for the specific patient population diagnosed with vascular disease. Addressing risk factors with treatment such as antiplatelet therapy and assessing blood pressure, lipid control and smoking within this patient population are common annual assessments and treatment for patients diagnosed with vascular disease. Management of blood pressure and lipids and encouraging patients to avoid smoking and maintain an antiplatelet treatment is beneficial	daily aspirin use One commenter provided general support for this measure but opposed its use due to its target population and emphasis on numerical value targets as numerical targets as they believe numerical targets provide an incentive to treat tests rather than symptoms. We respectfully disagree, as this composite encompasses measurements that address risk factors for the specific patient population diagnosed with vascular disease. Addressing risk factors with treatment such as antiplatelet therapy and assessing blood pressure, lipid control and smoking within this patient population are common annual assessments and treatment for patients diagnosed with vascular disease. Management of blood pressure and lipids and encouraging patients to avoid smoking and maintain an antiplatelet treatment is beneficial for this patient population.	daily aspirin use One commenter provided general support for this measure but opposed its use due to its target population and emphasis on numerical value targets as numerical targets as they believe numerical targets provide an incentive to treat tests rather than symptoms. We respectfully disagree, as this composite encompasses measurements that address risk factors for the specific patient population diagnosed with vascular disease. Addressing risk factors with treatment such as antiplatelet therapy and assessing blood pressure, lipid control and smoking within this patient population are common annual assessments and treatment for patients diagnosed with vascular disease. 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Management of blood pressure and lipids and encouraging patients to avoid smoking and maintain an antiplatelet treatment is beneficial for this patient population.	daily aspirin use One commenter provided general support for this measure but opposed its use due to its target population and emphasis on numerical value targets as numerical targets as they believe numerical targets provide an incentive to treat tests rather than symptoms. We respectfully disagree, as this composite encompasses measurements that address risk factors for the specific patient population diagnosed with vascular disease. Addressing risk factors with treatment such as antiplatelet therapy and assessing blood pressure, lipid control and smoking within this patient population are common annual assessments and treatment for patients diagnosed with vascular disease. Management of blood pressure and lipids and encouraging patients to avoid smoking and maintain an antiplatelet treatment is beneficial for this patient population.	daily aspirin use One commenter provided general support for this measure but opposed its use due to its target population and emphasis on numerical value targets as numerical targets as they believe numerical targets provide an incentive to treat tests rather than symptoms. We respectfully disagree, as this composite encompasses measurements that address risk factors for the specific patient population diagnosed with vascular disease. Addressing risk factors with treatment such as antiplatelet therapy and assessing blood pressure, lipid control and smoking within this patient population are common annual assessments and treatment for patients diagnosed with vascular disease. Management of blood pressure and lipids and encouraging patients to avoid smoking and maintain an antiplatelet treatment is beneficial for this patient population.	daily aspirin use One commenter provided general support for this measure but opposed its use due to its target population and emphasis on numerical value targets as numerical targets as they believe numerical targets provide an incentive to treat tests rather than symptoms. We respectfully disagree, as this composite encompasses measurements that address risk factors for the specific patient population diagnosed with vascular disease. Addressing risk factors with treatment such as antiplatelet therapy and assessing blood pressure, lipid control and smoking within this patient population are common annual assessments and treatment for patients diagnosed with vascular disease. Management of blood pressure and lipids and encouraging patients to avoid smoking and maintain an antiplatelet treatment is beneficial for this patient population.

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality	Keporting Programs
			variety of eligible professionals. Therefore, we are finalizing this measure for inclusion in PQRS beginning in 2014.								
N/A/ N/A‡		Communication and Care Coordination	Total Knee Replacement: Shared Decision-Making: Trial of Conservative (Non-surgical) Therapy: Percentage of patients undergoing a total knee replacement with documented shared decision- making with discussion of conservative (non-surgical) therapy prior to the procedure This measure was finalized for	AAHKS					X		
N/A/ N/A‡		Patient Safety	prs Final Rule. Total Knee Replacement: Venous Thromboembolic and Cardiovascular Risk Evaluation: Percentage of patients regardless of age or gender undergoing a total knee replacement who are evaluated for the presence or absence of venous thromboembolic and cardiovascular risk factors within 30 days prior to the procedure including	AAHKS					X		

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality	Keporung Programs
			history of Deep Vein Thrombosis, Pulmonary Embolism, Myocardial Infarction, Arrhythmia and Stroke								
			One commenter expressed general support for the inclusion of this measure. We appreciate the commenter's feedback and are finalizing it for inclusion in 2014 PQRS								
N/A/ N/A‡		Patient Safety	Total Knee Replacement: Preoperative Antibiotic Infusion with Proximal Tourniquet: Percentage of patients regardless of age undergoing a total knee replacement who had the prophylactic antibiotic completely infused prior to the inflation of the proximal tourniquet This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule.	AAHKS					X		
N/A/ N/A‡		Patient Safety	Total Knee Replacement: Identification of Implanted Prosthesis in Operative Report: Percentage of patients regardless of age or gender undergoing total knee	AAHKS					X		

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality	Reporting Programs
			replacement whose operative report identifies the prosthetic implant specifications including the prosthetic implant manufacturer, the brand name of prosthetic implant and the size of prosthetic implant								
			This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule.								
N/A/N/A‡		Effective Clinical Care	Anastomotic Leak Intervention: Percentage of patients aged 18 years and older who required an anastomotic leak intervention following gastric bypass or colectomy surgery	ACS					X		
			This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule.								
N/A/N/A‡		Effective Clinical Care	Unplanned Reoperation within the 30 Day Postoperative Period: Percentage of patients aged 18 years and older who had any unplanned reoperation within the 30 day postoperative period	ACS					X		
			This measure was finalized for								

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting	Programs
			inclusion in 2014 PQRS in the CY 2013 PFS Final Rule.								
N/A/N/A‡		Effective Clinical Care	Unplanned Hospital Readmission within 30 Days of Principal Procedure: Percentage of patients aged 18 years and older who had an unplanned hospital readmission within 30 days of principal procedure This measure was finalized for inclusion in 2014 PQRS in the CY 2013	ACS					X		
NT/A /NT/A ±			PFS Final Rule.	A CC					N/		
N/A/N/A‡		Effective Clinical Care	Surgical Site Infection (SSI): Percentage of patients aged 18 years and older who had a surgical site infection (SSI)	ACS					X		
			This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule.								
N/A/N/A‡		Person and Caregiver- Centered Experience and Outcomes	Patient-Centered Surgical Risk Assessment and Communication: Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical	ACS		X			X		

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure	Claims	Registry	EHR	GPRO (Web Interface)*	Measures	Other Quality	Reporting Programs
			team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon One commenter requested clarification regarding the target patient population and the patient-specific risk calculator. The commenter encouraged CMS to provide clarification to providers regarding measure applicability and guidance on which measures CMS believes are best suited for an eligible professional or group practice to report. Please note that these questions are not typically addressed in rulemaking. We urge the commenters to review the 2014 PQRS program documentation and contact the QualityNet Help Desk for assistance with reporting applicable measures.								
N/A/		Communication and	Optimizing Patient Exposure to	AMA-PCPI					X		
N/A‡		Care Coordination	Ionizing Radiation: Utilization of a Standardized Nomenclature for Computed Tomography (CT)								

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality	Reporting	Programs
			Imaging Description: Percentage of computed tomography (CT) imaging reports for all patients, regardless of age, with the imaging study named according to a standardized nomenclature and the standardized nomenclature is used in institution's computer systems									
			This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule.									
N/A/ N/A‡		Patient Safety	Optimizing Patient Exposure to Ionizing Radiation: Count of Potential High Dose Radiation Imaging Studies: Computed Tomography (CT) and Cardiac Nuclear Medicine Studies: Percentage of computed tomography (CT) and cardiac nuclear medicine (myocardial perfusion studies) imaging reports for all patients, regardless of age, that document a count of known previous CT (any type of CT) and cardiac nuclear medicine (myocardial perfusion) studies that the patient has	AMA-PCPI					X			

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality	Reporting Programs
			received in the 12-month period prior to the current study								
			This measure was finalized for								
			inclusion in 2014 PQRS in the CY 2013								
N/A/		Dations Cofee	PFS Final Rule.	AMA DODI					X		
N/A/ N/A‡		Patient Safety	Optimizing Patient Exposure to	AMA-PCPI					X		
N/A+			Ionizing Radiation: Reporting to a Radiation Dose Index Registry:								
			Percentage of total computed								
			tomography (CT) studies performed for								
			all patients, regardless of age, that are								
			reported to a radiation dose index								
			registry AND that include at a								
			minimum selected data elements								
			This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule.								
N/A/		Communication and	Optimizing Patient Exposure to	AMA-PCPI					X		
N/A‡		Care Coordination	Ionizing Radiation: Computed								
			Tomography (CT) Images Available								
			for Patient Follow-up and								
			Comparison Purposes: Percentage of								
			final reports for computed tomography								
			(CT) studies performed for all patients,								

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality	Reporting Programs
			regardless of age, which document that Digital Imaging and Communications in Medicine (DICOM) format image data are available to non-affiliated external entities on a secure, media free, reciprocally searchable basis with patient authorization for at least a 12-month period after the study								
			This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule.								
N/A/ N/A‡		Communication and Care Coordination	Optimizing Patient Exposure to Ionizing Radiation: Search for Prior Computed Tomography (CT) Imaging Studies Through a Secure, Authorized, Media-Free, Shared Archive: Percentage of final reports of computed tomography (CT) studies performed for all patients, regardless of age, which document that a search for Digital Imaging and Communications in Medicine (DICOM) format images was conducted for prior patient CT imaging studies completed at non- affiliated external entities within the	AMA-PCPI					X		

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [*]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality	Reporting Programs
			past 12-months and are available through a secure, authorized, media free, shared archive prior to an imaging study being performed								
			This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule.								
N/A/ N/A‡		Communication and Care Coordination	Optimizing Patient Exposure to Ionizing Radiation: Appropriateness: Follow-up CT Imaging for Incidentally Detected Pulmonary Nodules According to Recommended Guidelines: Percentage of final reports for CT imaging studies of the thorax for patients aged 18 years and older with documented follow-up recommendations for incidentally detected pulmonary nodules (eg, follow-up CT imaging studies needed or that no follow-up is needed) based at a minimum on nodule size AND patient risk factors This measure was finalized for inclusion in 2014 PQRS in the CY 2013	AMA-PCPI					X		

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
			PFS Final Rule.							
0060/ N/A‡	148v2	Effective Clinical Care	Hemoglobin A1c Test for Pediatric Patients: Percentage of patients 5-17 years of age with diabetes with a HbA1c test during the measurement period	NCQA			X			MU2
			This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule.							
0108/ N/A‡	136v3	Effective Clinical Care	ADHD: Follow-Up Care for Children Prescribed Attention- Deficit/Hyperactivity Disorder (ADHD) Medication: Percentage of children 6-12 years of age and newly dispensed a medication for attention- deficit/hyperactivity disorder (ADHD) who had appropriate follow-up care. Two rates are reported. a. Percentage of children who had one follow-up visit with a practitioner with prescribing authority during the 30-Day Initiation Phase. b. Percentage of children who remained on ADHD medication for at least 210 days and who, in addition to the visit in the Initiation Phase, had at least two additional follow-up visits with a	NCQA			X			MU2

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure	Claims	Registry	EHR	GPRO (Web Interface)*	Measures	Other Quality	Keporting Programs
			practitioner within 270 days (9 months)								
			after the Initiation Phase ended.								
			This measure was finalized for								
			inclusion in 2014 PQRS in the CY 2013								
			PFS Final Rule.								
0110/	169v2	Effective Clinical Care	Bipolar Disorder and Major	CQAIMH			X			MU	J2
N/A‡			Depression: Appraisal for alcohol or								
			chemical substance use: Percentage of								
			patients with depression or bipolar								
			disorder with evidence of an initial								
			assessment that includes an appraisal								
			for alcohol or chemical substance use.								
			This measure was finalized for								
			inclusion in 2014 PQRS in the CY 2013								
			PFS Final Rule.								
0403/	62v2	Effective Clinical Care	HIV/AIDS: Medical Visit: Percentage	NCQA			X				
N/A‡			of patients, regardless of age, with a							ΜU	J2
			diagnosis of HIV/AIDS with at least								
			two medical visits during the								
			measurement year with a minimum of								
			90 days between each visit								
			This measure was finalized for								
			inclusion in 2014 PQRS in the CY 2013								

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
			PFS Final Rule.							
0608/ N/A‡	158v2	Effective Clinical Care	Pregnant women that had HBsAg testing: This measure identifies pregnant women who had a HBsAg (hepatitis B) test during their pregnancy.	OptumInsight			X			MU2
			This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule.							
0710/N/A‡	159v2	Effective Clinical Care	Depression Remission at Twelve Months: Adult patients age 18 and older with major depression or dysthymia and an initial PHQ-9 score > 9 who demonstrate remission at twelve months defined as PHQ-9 score less than 5. This measure applies to both patients with newly diagnosed and existing depression whose current PHQ-9 score indicates a need for treatment	MNCM			X			MU2
			One commenter was concerned that this measure was only proposed for inclusion using the EHR-based reporting option. In an effort to							

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure	Claims	Registry	EHR	GPRO (Web	Measures	Groups	Other Quality	Reporting	Programs
			completely align programs, all measures in the EHR Incentive Program have been adopted for 2014 PQRS EHR-based reporting option. For CY 2014, CMS was unable to determine the feasibility of incorporation of this measure for other reporting options; however, CMS intends to continue working toward complete alignment of measure specifications across programs whenever possible and incorporation of this measure in other PQRS reporting options may considered in the future. This measure identifies specific gaps in care and encourages more provider reporting to assess quality care while allowing specialty professionals to participate in the program. For these reasons, we are finalizing this measure as proposed for PQRS beginning in 2014.										
0712/ N/A‡	160v2	Effective Clinical Care	Depression Utilization of the PHQ-9 Tool: Adult patients age 18 and older with the diagnosis of major depression	MNCM			X				M	U2	

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures	Other Quality	Reporting Programs	* * V&* ****
			or dysthymia who have a PHQ-9 tool									
			administered at least once during a 4									
			month period in which there was a									
			qualifying visit.									
			One commenter was concerned that this									
			measure was only proposed for									
			inclusion using the EHR-based									
			reporting option. In an effort to									
			completely align programs, all									
			measures in the EHR Incentive									
			Program have been adopted for 2014									
			PQRS EHR-based reporting option. For									
			CY 2014, CMS was unable to									
			determine the feasibility of									
			incorporation of this measure for other									
			reporting options; however, CMS									
			intends to continue working toward									
			complete alignment of measure									
			specifications across programs whenever possible and incorporation of									
			*									
			this measure in other PQRS reporting options may considered in the future.									
			options may considered in the future.									
			This measure identifies specific gaps in									
			care and encourages more provider									

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description ⁴	Measure	Claims	Registry	EHR	GPRO (Web Interface)*	Measures	Other Quality	Reporting Programs
			reporting to assess quality care while allowing specialty professionals to participate in the program. For these reasons, we are finalizing this measure as proposed for PQRS beginning in 2014.								
1401/ N/A‡	82v1	Community/ Population Health	Maternal Depression Screening: The percentage of children who turned 6 months of age during the measurement year, who had a face-to-face visit between the clinician and the child during child's first 6 months, and who had a maternal depression screening for the mother at least once between 0 and 6 months of life. One commenter was concerned that this measure was only proposed for inclusion using the EHR-based reporting option. In an effort to completely align programs, all measures in the EHR Incentive Program have been adopted for 2014	NCQA			X			М	J2
			PQRS EHR-based reporting option. For CY 2014, CMS was unable to determine the feasibility of								

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web	Measures	Groups	Other Quality Reporting	Programs
			incorporation of this measure for other reporting options; however, CMS intends to continue working toward complete alignment of measure specifications across programs whenever possible and incorporation of this measure in other PQRS reporting options may considered in the future. This measure identifies specific gaps in care and encourages more provider reporting to assess quality care while allowing specialty professionals to participate in the program. For these reasons, we are finalizing this measure as proposed for PQRS beginning in 2014.									
N/A/ N/A‡	65v3	Effective Clinical Care	Hypertension: Improvement in Blood Pressure: Percentage of patients aged 18-85 years of age with a diagnosis of hypertension whose blood pressure improved during the measurement period. One commenter expressed concern with attaching numerical targets to blood	CMS			X				MU	2

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures	Other Quality	Reporting Programs
			pressure measures, stating this measure								
			still encourages a focus on management								
			of numbers over management of								
			patients. CMS appreciates the								
			commenters' feedback and								
			acknowledges that the focus of								
			medicine should be with the								
			management of the patients.								
			Analytically, this measure excludes								
			patients that may have clinical								
			conditions such as end-stage renal								
			disease, pregnancy and/or renal								
			transplant, hemodialysis or peritoneal								
			dialysis. Exclusion of these populations								
			is an attempt to allow the blood								
			pressure measurement as guide lined by								
			JNC-7 to apply to a more generalized								
			population of patient diagnosed with								
			hypertension. In an effort to completely								
			align programs, all measures in the								
			EHR Incentive Program have been								
			adopted for the PQRS EHR-based								
			reporting option beginning in 2014.								
			Alignment of measures contained								
			within multiple CMS reporting								
			programs eases the burden of reporting								

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting	Programs
			and encourages eligible professionals to submit quality clinical data on care provided for Medicare beneficiaries. For these reasons, we are finalizing this measure as proposed.								
N/A/ N/A‡	50v2	Communication and Care Coordination	Closing the referral loop: receipt of specialist report: Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred. This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule.	CMS			X			MU2	
N/A/N/A‡	66v2	Person and Caregiver- Centered Experience and Outcomes	Functional Status Assessment for Knee Replacement: Percentage of patients aged 18 years and older with primary total knee arthroplasty (TKA) who completed baseline and follow-up (patient-reported) functional status assessments. This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule.	CMS			X			MU2	,

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure	Claims	Registry	EHR	GPRO (Web Interface)*	Measures	Other Quality Reporting	Programs
N/A/ N/A‡	56v2	Person and Caregiver- Centered Experience and Outcomes	Functional Status Assessment for Hip Replacement: Percentage of patients aged 18 years and older with primary total hip arthroplasty (THA) who completed baseline and follow-up (patient-reported) functional status assessments This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule.	CMS			X			MU2	
N/A/ N/A‡	90v3	Person and Caregiver-Centered Experience and Outcomes	Functional Status Assessment for Complex Chronic Conditions: Percentage of patients aged 65 years and older with heart failure who completed initial and follow-up patient-reported functional status assessments One commenter appreciates the value of assessing functional status in heart failure patients, however, is concerned the measure requires a questionnaire and the potential of associated cost. CMS would like to note that many of the assessment tools are readily available to the public and generally do	CMS			X			MU2	

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting	Programs
			not have an associated cost. We are finalizing this measure as for inclusion in the EHR-based reporting option for PQRS beginning in 2014.								
N/A/N/A‡	75v2	Effective Clinical Care	Children Who Have Dental Decay or Cavities: Percentage of children, age 0-20 years, who have had tooth decay or cavities during the measurement period. This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule.	CMS			X			MU2	
N/A/N/A‡	74v3	Effective Clinical Care	Primary Caries Prevention Intervention as Offered by Primary Care Providers, including Dentists: Percentage of children, age 0-20 years, who received a fluoride varnish application during the measurement period. This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule.	CMS			X			MU2	
N/A/N/A‡	179v2	Patient Safety	ADE Prevention and Monitoring: Warfarin Time in Therapeutic Range: Average percentage of time in	CMS			X			MU2	

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures	Orber Ouality	Reporting	Programs
			which patients aged 18 and older with									
			atrial fibrillation who are on chronic									
			warfarin therapy have International									
			Normalized Ratio (INR) test results									
			within the therapeutic range (i.e., TTR)									
			during the measurement period.									
			One commenter supported the inclusion									
			of this measure but cautioned against									
			the use of a single measure and									
			methodology for tracking the									
			appropriateness of anticoagulant									
			therapy. CMS appreciates the									
			commenters support and feedback.									
			This measure is analytically challenging									
			for reporting in a claims-based or									
			registry-based mechanisms, therefore is									
			currently implemented as an EHR									
			measure. Patients with atrial fibrillation									
			are at an increased risk for stroke,									
			therefore CMS agrees that this measure									
			is a valuable measurement within									
			PQRS and the EHR Incentive Program.									
			In an effort to completely align									
			programs, all measures in the EHR									
			Incentive Program have been adopted									

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality	Keporting Programs
			for 2014 PQRS EHR-based reporting option. CMS appreciates the suggestion and encourages societies and measure developers to develop measures they believe address possible gaps in quality reporting. We are finalizing this measure for inclusion, as proposed,								
N/A/N/A‡	77v2	Effective Clinical Care	beginning in 2014. HIV/AIDS: RNA Control for Patients with HIV: Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS, with at least two visits during the measurement year, with at least 90 days between each visit, whose most recent HIV RNA level is <200 copies/mL. This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule.	CMS			X			MU	J2
1365/ N/A‡	177v2	Patient Safety	Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment: Percentage of patient visits for those patients aged 6 through 17 years with a diagnosis of major depressive disorder with an assessment	AMA-PCPI			X			MU	J2

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web	Interface)" Measures	Groups	Other Quality	Reporting	Programs
			for suicide risk										
			One commenter supported the addition of this measure and it's alignment with the EHR Incentive Program. We appreciate the support of this measure and our actions to align quality reporting programs. Another commenter was concerned that this measure was only proposed for inclusion using the EHR-based reporting option. For CY 2014, CMS was unable to determine the feasibility of incorporation of this measure for other reporting options; however, CMS intends to continue working toward complete alignment of measure specifications across programs whenever possible and incorporation of this measure in other PQRS reporting options may considered in the future. This measure identifies specific gaps in care and encourages more provider reporting to assess quality care while allowing specialty professionals to										

NQF/ PQRS	CMS E-Measure	National Quality Strategy Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
			participate in the program. For these reasons, we are finalizing this measure as proposed for PQRS beginning in 2014.							

[‡] This measure is new to the Physician Quality Reporting System and has been adopted for reporting beginning in CY 2014.

Table 53 includes the measures we proposed to include in the PQRS measure set for 2014 and beyond but, for the reasons specified in Table 53, we are not finalizing for 2014 and beyond.

TABLE 53: Measures Proposed for Inclusion in the Physician Quality Reporting System Measure Beginning in 2014 that are Not Finalized to be Included in the Physician Quality Reporting System Measure Beginning in 2014

NQF/ PQRS	NQS Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*		Cenci Quanty Reporting	Виолиомы
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[¥] Titles and descriptions in this table are aligned with the 2014 Physician Quality Reporting System Claims and Qualified Registry measure titles and descriptions, and may differ based on reporting mechanism within PQRS. Additionally, there may be tittle and description variations for the same measure across other quality reporting programs. Please reference the National Quality Forum (NQF) and Physician Quality Reporting System numbers for clarification. This column also contains summary of public comments and CMS's responses, if applicable.

N/A/	Patient Safety	Atopic Dermatitis: Overuse: Role of Antihistamine:	AMA-PCPI	X		
N/A		Percentage of patients aged 25 years or younger seen at one				
		or more visits within a 12-month period with a diagnosis of				
		atopic dermatitis, who did not have a diagnosis of allergic				
		rhinitis or urticaria, who were prescribed oral nonsedating antihistamines				
		One commenter supported the inclusion of this measure as it would gather data on the "percentage of patients aged 25 years or younger seen at one or more visits within a 12-				
		month period with a diagnosis of atopic dermatitis, who did				
		not have a diagnosis of allergic rhinitis or urticaria, who				
		were prescribed oral nonsedating antihistamines." Another				
		commenter did not support inclusion of this measure in the				
		PQRS program.				
		We agree with the latter commenter that this measure should not be included and therefore, we are not finalizing it for inclusion in 2014 PQRS.				
N/A/	Effective	Neurosurgery: Initial Visit: The percentage of patients	AANS/CNS	X		
N/A	Clinical Care	aged 18 through 80 years with a diagnosis of a neurosurgical				
		procedure or pathology who had function assessed during the				
		initial visit to the clinician for the episode of the condition				
		The measure owner withdrew support of this measure and therefore, we are not finalizing it for inclusion in 2014 PQRS.				

0372/N/A	Patient Safety	VTE-2: Intensive Care Unit Venous Thromboembolism Prophylaxis: This measure assesses the number of patients who received VTE prophylaxis or have documentation why no VTE prophylaxis was given the day of or the day after the initial admission (or transfer) to the Intensive Care Unit (ICU) or surgery end date for surgeries that start the day of or the day after ICU admission (or transfer)	The Joint Commission	X	IQR
		Several commenters appreciate CMS' efforts to align the PQRS measures with other quality reporting program but were concerned about the ability to implement this measure in PQRS. CMS appreciates the support of its actions to align quality reporting programs with the inclusion of the IQR measures. However, CMS is deferring the incorporation of the IQR measures until 2015 due to operational issues with implementation. As such, we are not finalizing this measure for inclusion in 2014 PQRS.			
N/A/N/A	Patient Safety	VTE-4: Venous Thromboembolism Patients Receiving Unfractionated Heparin with Dosages/Platelet Count Monitoring by Protocol: This measure assesses the number of patients diagnosed with confirmed VTE who received intravenous (IV) UFH therapy dosages AND had their platelet counts monitored using defined parameters such as a nomogram or protocol. Several commenters appreciate CMS' efforts to align the PQRS measures with other quality reporting program but were concerned about the ability to implement this measure in PQRS. CMS appreciates the support of its actions to align quality reporting programs with the inclusion of the IQR measures. However, CMS is deferring the incorporation of the IQR measures until 2015 due to operational issues with implementation. As such, we are not finalizing this measure for inclusion in 2014 PQRS.	The Joint Commission	X	IQR

0495/N/A	Communication	ED-1a: Median Time from ED Arrival to ED Departure for	CMS	X		IQR
	and Care	Admitted ED Patients - Overall Rate: Median time from				
	Coordination	emergency department arrival to time of departure from the				
	Coordination	emergency room for patients admitted to the facility from the				
		emergency department				
		C 1 '- CMC' CC - 1' - 1 DODG				
		Several commenters appreciate CMS' efforts to align the PQRS				
		measures with other quality reporting program but were concerned				
		about the ability to implement this measure in PQRS. CMS				
		appreciates commenter's support of this measure but is deferring				
		the incorporation of the IQR measures until 2015 due to				
		operational issues with implementation. As such, we are not				
		finalizing this measure for inclusion in 2014 PQRS.				

1659/N/A	Community/	IMM-1c: Pneumococcal Immunization (PPV23) – High	CMS	X	IQR
	Population	Risk Populations (Age 5 through 64 years): This			
	Health	prevention measure addresses acute care hospitalized			
		inpatients 65 years of age and older (IMM-1b) AND			
		inpatients aged between 5 and 64 years (IMM-1c) who are			
		considered high risk and were screened for receipt of			
		pneumococcal vaccine and were vaccinated prior to			
		discharge if indicated. The numerator captures two activities;			
		screening and the intervention of vaccine administration			
		when indicated. As a result, patients who had documented			
		contraindications to pneumococcal vaccine, patients who			
		were offered and declined pneumococcal vaccine and			
		patients who received pneumococcal vaccine anytime in the			
		past are captured as numerator events			
		Several commenters appreciate CMS' efforts to align the			
		PQRS measures with other quality reporting programs. CMS			
		appreciates the support of its actions to align quality			
		reporting programs with the inclusion of the IQR measures.			
		Other commenters did not support inclusion of this measure			
		in the PQRS program due to its suspension from the IQR			
		program and difficulties implementing this measure in			
		PQRS. We agree with the latter commenters that this			
		measure should not be included and therefore, we are not			
		finalizing it for inclusion in 2014 PQRS. Implementation of			
		all IQR measures in PQRS has been deferred until 2015.			

0147/N/A	Patient Safety	PN-6: Initial Antibiotic Selection for CAP in	CMS	X	IQR
		Immunocompetent			
		Patient: Immunocompetent patients with Community-Acquired Pneumonia who receive an initial antibiotic regimen during the first 24 hours that is consistent with current guidelines			
		Several commenters appreciate CMS' efforts to align the PQRS measures with other quality reporting programs. CMS appreciates the support of its actions to align quality reporting programs with the inclusion of the IQR measures. Other commenters did not support inclusion of this measure due to difficulties implementing this measure in PQRS. We agree with the latter commenters that this measure should not be included and therefore, we are not finalizing it for inclusion in 2014 PQRS. Implementation of all IQR measures in PQRS has been deferred until 2015.			
0495/N/A	Communication	ED-1d: Median Time from ED Arrival to ED Departure for	CMS	X	IQR
0 19 27 2 11 2 2	and Care	Admitted Patients - Psychiatric/Mental Health Patients:			
	Coordination	Median time from emergency department arrival to time of			
		departure from the emergency room for patients admitted to the facility from the emergency department			
		One commenter appreciates CMS' efforts to align the PQRS measures with other quality reporting programs. CMS appreciates the support of its actions to align quality reporting programs with the inclusion of the IQR measures. Several commenters did not support inclusion of this measure due to difficulties implementing this measure in PQRS. We agree with the latter commenters that this measure should not be included and therefore, we are not finalizing it for inclusion in 2014 PQRS. Implementation of all IQR measures in PQRS has been deferred until 2015.			

0166/N/A	Communication and Care Coordination	Providers and Systems Survey: 27-items survey instrument with 7 domain-level composites including: communication with doctors, communication with nurses, responsiveness of hospital staff, pain control, communication about medicines, cleanliness and quiet of the hospital environment, and discharge information One commenter appreciates CMS' efforts to align the PQRS measures with other quality reporting programs. CMS appreciates the support of its actions to align quality reporting programs with the inclusion of the IQR measures. Several commenters did not support inclusion of this measure due to difficulties implementing this measure in PQRS. We agree with the latter commenters that this measure should not be included and therefore, we are not finalizing it for inclusion in 2014 PQRS. Implementation of all IQR measures in PQRS has been deferred until 2015.	CMS	X			IQR
N/A/N/A	Effective	Ventral Hernia, Appendectomy, AV Fistula,	ACS			X	
	Clinical Care	Cholecystectomy, Thyroidectomy, Mastectomy +/-					
		Lymphadenectomy or SLNB, Partial Mastectomy or					
		Breast Biopsy/Lumpectomy +/- Lymphadenectomy or					
		SLNB: Iatrogenic Injury to Adjacent Organ/Structure:					
		Percentage of patients age 65 and older who had an					
		iatrogenic injury documented in the operative note,					
		postoperative note, or progress note. Iatrogenic injury is an					
		unplanned laceration, puncture, transection or cautery injury					
		to an adjacent structure (e.g., sphincters, vasculature, nerve,					
		other) that occurs during the index procedure, whether					
		recognized at the time of surgery or post-operatively.					
		Synonyms for the injury could include: hole, wound,					
		perforation, tear, injury, laceration, cautery injury, damage,					
		disruption, or defect					
		The measure owner withdrew support of this measure and					
		therefore, we are not finalizing it for inclusion in 2014 PQRS.					

N/A/N/A	Effective	Bariatric Laparoscopic or Open Roux-en Y Gastric	ACS		X	
	Clinical Care	Bypass, Bariatric Sleeve Gastrectomy, and Colectomy:				
		Iatrogenic Injury to Adjacent Organ/Structure:				
		Percentage of patients age 65 and older who had an				
		iatrogenic injury documented in the operative note,				
		postoperative note, or progress note. Iatrogenic injury is an				
		unplanned laceration, puncture, transection or cautery injury				
		to an adjacent structure (e.g., sphincters, vasculature, nerve,				
		other) that occurs during the index procedure, whether				
		recognized at the time of surgery or post-operatively.				
		Synonyms for the injury could include: hole, wound,				
		perforation, tear, injury, laceration, cautery injury, damage,				
		disruption, or defect				
		The measure owner withdrew support of this measure and				
		therefore, we are not finalizing it for inclusion in 2014				
		PQRS.				

[¥] Titles and descriptions in this table are aligned with the 2014 Physician Quality Reporting System Claims and Qualified Registry measure titles and descriptions, and may differ based on reporting mechanism within PQRS. Additionally, there may be tittle and description variations for the same measure across other quality reporting programs. Please reference the National Quality Forum (NQF) and Physician Quality Reporting System numbers for clarification.

In Table 54, we specify the measures we proposed to remove from reporting under the PQRS and whether, based on the comments received, we are finalizing our proposal to remove these measures from reporting under the PQRS in 2014. Please note that the rationale we have for finalizing removal of each measure is specified after the measure title and description.

TABLE 54: Measures To Be Removed from Reporting in the Physician Quality Reporting System in 2014

NQF/ PQRS	NQS Domain	Measure Title and Description [‡]	Measure Steward	Claims	Registry		GPRO (Web Interface)*		, , ,	Programs
0061/3	Effective Clinical Care	Control: Percentage of patients aged 18 through 75 years with diabetes mellitus who had most recent blood pressure in control (less than 140/90 mmHg) Rationale: Measure deletion due to direction of eliminating duplicative measures within PQRS. One commenter supported the removal of this measure, while another commenter cautioned against removal of this measure until new guidelines are established for development of a comprehensive blood pressure control measure that is clinically relevant for Ischemic Vascular Disease and Diabetes. A third commenter cautioned against the removal due to the importance of blood pressure control for patients with diabetes. Additionally, commenters were concerned with the removal of this measure as it impacts the number of measures available to eligible professionals.	NCQA	X	X	X		X	MU1	

NQF/ PQRS	NQS Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures	Other Quality Reporting	Programs
		We appreciate the comments and understand the concerns. Due to our desire to move away from claims-based reporting, we are not finalizing this measure for inclusion in 2014 PQRS.								
N/A/ 86	Effective Clinical Care	Hepatitis C: Antiviral Treatment Prescribed: Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C who were prescribed at a minimum peginterferon and ribavirin therapy within the 12-month reporting period Rationale: Measure lost NQF Endorsement/Measure Owner Support. One commenter supported the removal of this measure as it has been retired from the medical professional society's measure set. We appreciate the commenters feedback and are not finalizing this measure for reporting under PQRS.	AMA-PCPI	X	X			X		
N/A/ 89	Effective Clinical Care	Hepatitis C: Counseling Regarding Risk of Alcohol Consumption: Percentage of patients aged 18 years and older with a diagnosis of hepatitis C who were counseled	AMA-PCPI	X	X			X		

NQF/ PQRS	NQS Domain	Measure Title and Description[‡]	Measure Steward	Claims	Registry	EHR	GPRO (Web	Measures	Groups Other Quality	Reporting	Programs
		about the risks of alcohol use at least once within 12-months Rationale: Measure lost NQF Endorsement/Measure Owner Support. One commenter supported the removal of this measure as it has been retired from the medical professional society's measure set. We appreciate the commenters feedback and are not finalizing this measure for reporting under PQRS.									
N/A/ 90	Effective Clinical Care	Hepatitis C: Counseling Regarding Use of Contraception Prior to Antiviral Therapy: Percentage of female patients aged 18 through 44 years and all men aged 18 years and older with a diagnosis of chronic hepatitis C who are receiving antiviral treatment who were counseled regarding contraception prior to the initiation of treatment Rationale: Measure lost NQF Endorsement/Measure Owner Support.	AMA-PCPI	X	X			X			

NQF/ PQRS	NQS Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
		One commenter supported the removal of this measure as it has been retired from the medical professional society's measure set. We appreciate the commenters feedback and are not finalizing this measure for reporting under PQRS.							
N/A/ 161	Effective Clinical Care	HIV/AIDS: Adolescent and Adult Patients with HIV/AIDS Who Are Prescribed Potent Antiretroviral Therapy: Percentage of patients with a diagnosis of HIV/AIDS aged 13 years and older: who have a history of a nadir CD4+ cell count below 350/mm³ or who have a history of an AIDS-defining condition, regardless of CD4+ cell count; or who are pregnant, regardless of CD4+ cell count or age, who were prescribed potent antiretroviral therapy	AMA- PCPI/NCQA		X			X	
		Rationale: Measure lost NQF Endorsement/Measure Owner Support. CMS solicited but received no comments on this measure. Therefore, for the reasons we stated in the proposed rule, we are finalizing our proposal to retire this measure from							

NQF/ PQRS	NQS Domain	Measure Title and Description[‡]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures	Other Quality	Reporting Programs
		PQRS beginning in 2014.								
N/A/ 162	Effective Clinical Care	HIV/AIDS: HIV RNA Control After Six Months of Potent Antiretroviral Therapy: Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS who are receiving potent antiretroviral therapy, who have a viral load below limits of quantification after at least 6 months of potent antiretroviral therapy or patients whose viral load is not below limits of quantification after at least 6 months of potent antiretroviral therapy and have documentation of a plan of care Rationale: Measure lost NQF Endorsement/Measure Owner Support.	AMA- PCPI/NCQA		X			X		
N/A/	Community/Population	CMS solicited but received no comments on this measure. We are finalizing our proposal to retire this measure from PQRS beginning in 2014. Hepatitis C: Hepatitis B Vaccination in	AMA- PCPI	X	X					
184	Health	Patients with HCV: Percentage of patients aged 18 years and older with a diagnosis of hepatitis C who received at least one	AMA-TOTI	Λ	Λ					

NQF/ PQRS	NQS Domain	Measure Title and Description [‡]	Measure Steward	Claims	Registry	EHR	GPRO (Web	Measures	Groups Other Quality	Reporting	Programs
		injection of hepatitis B vaccine, or who have documented immunity to hepatitis B									
		Rationale: Measure lost NQF Endorsement/Measure Owner Support. Two commenters did not agree with the removal of this measure and requested that CMS reconsider, stating this measure addresses an important aspect of care. Additionally, this measure is paired with PQRS 183 which was proposed for continued inclusion for the 2014 program year. We appreciate the commenter's feedback, but, based on the rationale provided above, we									
		are not retaining this measure for reporting under PQRS.									
N/A/ 188	Communication and Care Coordination	Referral for Otologic Evaluation for Patients with Congenital or Traumatic Deformity of the Ear: Percentage of patients aged birth and older referred to a physician (preferably a physician with training in disorders of the ear) for an otologic evaluation subsequent to an audiologic evaluation after presenting with a	AQC	X	X						

NQF/ PQRS	NQS Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web	Measures	Groups	Other Quanty Reporting	Programs
		congenital or traumatic deformity of the ear (internal or external) Rationale: Measure deletion due to low utilization and lack of clinical relevance for the Medicare population. CMS solicited but received no comments on this measure. Therefore, for the reasons provided above, we are finalizing our proposal to retire this measure from PQRS beginning in 2014.									
N/A/ 200	Effective Clinical Care	Heart Failure: Warfarin Therapy for Patients with Atrial Fibrillation: Percentage of all patients aged 18 and older with a diagnosis of heart failure and paroxysmal or chronic atrial fibrillation who were prescribed warfarin therapy Rationale: Measure lost NQF Endorsement/Measure Owner Support. One commenter did not support the retirement of this measure. Several commenters supported the removal of this	AMA-PCPI/ACCF/AHA			X				MU	1

NQF/ PQRS	NQS Domain	Measure Title and Description⁴	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
		measure as it has been retired from the medical professional society's measure set, while one commenter did not support the retirement, stating it is pertinent to the field of electrophysiology. We appreciate the commenters feedback and for the reasons identified, are not finalizing this measure for reporting under PQRS							
0073/201	Effective Clinical Care	Ischemic Vascular Disease (IVD): Blood Pressure Management: Percentage of patients aged 18 to 75 years with Ischemic Vascular Disease (IVD) who had most recent blood pressure in control (less than 140/90 mmHg) Rationale: Measure deletion due to direction of eliminating duplicative measures within PQRS. One commenter supported the removal of this measure. Another commenter cautioned against removal of this measure until new guidelines are established for development of a comprehensive blood pressure control measure that is clinically relevant for	NCQA	X	X	X		X	MU1

NQF/ PQRS	NQS Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures	Other Quality Reporting	Programs
		Ischemic Vascular Disease and Diabetes. Additionally, commenters were concerned with the removal of this measure as it impacts the number of measures available to eligible professionals. We appreciate the comments and understand the concerns. Due to our desire to move away from claims-based reporting, we are not finalizing this measure for inclusion in 2014 PQRS.								
0410/208	Effective Clinical Care	HIV/AIDS: Sexually Transmitted Disease Screening for Syphilis: Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS who were screened for syphilis at least once within 12 months Rationale: Measure owner combined NQF 0410 with NQF 0409. CMS solicited but received no comments on this measure. Therefore, we are finalizing our proposal to retire this measure from PQRS beginning in 2014.	AMA-PCPI/NCQA		X			X		
0445/209	Effective Clinical Care	Functional Communication Measure - Spoken Language Comprehension: Percentage of patients aged 16 years and older with a diagnosis of late effects of cerebrovascular disease (CVD) that make progress on the Spoken Language	ASHA		X					

NQF/ PQRS	NQS Domain	Measure Title and Description [‡]	Measure Steward	Claims	Registry	EHR	GPRO (Web	Measures	Groups	Other Quality	Reporting	Programs
		Comprehension Functional Communication Measure Rationale: Measure lost Measure Owner support. One commenter disagreed with CMS' decision to retire this measure due to the need for clinically relevant measures of outcome and quality for speech-language pathologists to report. We appreciate the commenters' feedback but for the reason above we are not retaining this measure for reporting under PQRS.										
0449/210	Effective Clinical Care	Functional Communication Measure – Attention: Percentage of patients aged 16 years and older with a diagnosis of late effects of cerebrovascular disease (CVD) that make progress on the Attention Functional Communication Measure Rationale: Measure lost Measure Owner support. One commenter disagreed with CMS'	ASHA		X							

NQF/ PQRS	NQS Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures	Groups Other Quality	Reporting	Programs
		decision to retire this measure due to the need for clinically relevant measures of outcome and quality for speech-language pathologists to report. We appreciate the commenters' feedback but we are not retaining this measure for reporting under PQRS for the reason above.									
0448/211	Effective Clinical Care	Functional Communication Measure – Memory: Percentage of patients aged 16 years and older with a diagnosis of late effects of cerebrovascular disease (CVD) that make progress on the Memory Functional Communication Measure Rationale: Measure lost Measure Owner support.	ASHA		X						
		One commenter disagreed with CMS' decision to retire this measure due to the need for clinically relevant measures of outcome and quality for speech-language pathologists to report. We appreciate the commenters' feedback but, for the reasons stated above, we are not retaining this measure for reporting under PQRS.									

NQF/ PQRS	NQS Domain	Measure Title and Description [‡]	Measure Steward	Claims	Registry	EHR	GPRO (Web	Measures	Groups Other Quality	Reporting	Programs
0447/212	Effective Clinical Care	Functional Communication Measure - Motor Speech: Percentage of patients aged 16 years and older with a diagnosis of late effects of cerebrovascular disease (CVD) that make progress on the Motor Speech Functional Communication Measure Rationale: Measure lost Measure Owner support. One commenter disagreed with CMS' decision to retire this measure due to the need for clinically relevant measures of outcome and quality for speech-language pathologists to report. We appreciate the commenters' feedback but, for the reasons stated above, we are not retaining this measure for reporting under PQRS.	ASHA		X						
0446/213	Effective Clinical Care	Functional Communication Measure – Reading: Percentage of patients aged 16 years and older with a diagnosis of late effects of cerebrovascular disease (CVD) that make progress on the Reading Functional Communication Measure	ASHA		X						

NQF/ PQRS	NQS Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures	Other Quality	Reporting	Programs
		Rationale: Measure lost Measure Owner									
		support.									
		One commenter disagreed with CMS' decision to retire this measure due to the need for clinically relevant measures of outcome and quality for speech-language pathologists to report. We appreciate the commenters' feedback but, for the reasons stated above, we are not retaining this measure for reporting under PQRS.									
0444/ 214	Effective Clinical Care	Functional Communication Measure - Spoken Language Expression: Percentage	ASHA		X						
		of patients aged 16 years and older with a									
		diagnosis of late effects of cerebrovascular disease (CVD) that make progress on the									
		Spoken Language Expression Functional									
		Communication Measure									
		Rationale: Measure lost Measure Owner support.									
		One commenter disagreed with CMS' decision to retire this measure due to the need for clinically relevant measures of									

NQF/ PQRS	NQS Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures	Other Quality	Reporting Programs
		outcome and quality for speech-language pathologists to report. We appreciate the commenters' feedback but, for the reasons stated above, we are not retaining this measure for reporting under PQRS.								
0442/215	Effective Clinical Care	Functional Communication Measure – Writing: Percentage of patients aged 16 years and older with a diagnosis of late effects of cerebrovascular disease (CVD) that make progress on the Writing Functional Communication Measure Rationale: Measure lost Measure Owner support. One commenter disagreed with CMS' decision to retire this measure due to the need for clinically relevant measures of outcome and quality for speech-language pathologists to report. We appreciate the commenters' feedback but, for the reasons stated above, we are not retaining this measure for reporting under PQRS.	ASHA		X					
0443/ 216	Effective Clinical Care	Functional Communication Measure – Swallowing: Percentage of patients aged 16	ASHA		X					

NQF/ PQRS	NQS Domain	Measure Title and Description [‡]	Measure Steward	Claims	Registry	EHR	GPRO (Web	Measures	Groups Other Ouglity	Reporting	Programs
		years and older with a diagnosis of late effects of cerebrovascular disease (CVD) that make progress on the Swallowing Functional Communication Measure									
		Rationale: Measure lost Measure Owner support. One commenter disagreed with CMS' decision to retire this measure due to the									
		need for clinically relevant measures of outcome and quality for speech-language pathologists to report. We appreciate the commenters' feedback but, for the reasons									
		stated above, we are not retaining this measure for reporting under PQRS.									
0013/ 237	Effective Clinical Care	Hypertension (HTN): Blood Pressure Measurement: Percentage of patient visits for patients aged 18 years and older with a diagnosis of HTN with blood pressure (BP) recorded	AMA-PCPI			X					
		Rationale: Deletion due to MU2 alignment. Several commenters supported the removal									

NQF/ PQRS	NQS Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Grouns	Other Quality Reporting	Programs
		of this measure as it has been retired from the medical professional society's measure set. We appreciate the commenters' feedback and are not finalizing this measure for reporting under PQRS.								
N/A/ 244	Effective Clinical Care	Hypertension: Blood Pressure Management: Percentage of patients aged 18 years and older with a diagnosis of hypertension seen within a 12 month period with a blood pressure < 140/90 mmHg OR patients with a blood pressure ≥ 140/90 mmHg and prescribed two or more anti- hypertensive medications during the most recent office visit Rationale: Measure deletion due to direction of eliminating duplicative measures within PQRS. Two commenters believed this measure addresses important aspects of care while another is concerned its impact on the number of measures available to eligible professionals.	AMA-PCPI/ACCF/AHA		X					

NQF/ PQRS	NQS Domain	Measure Title and Description⁴	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality	Keporting Programs
		We appreciate the comment and understand								
		the concerns. Due to our desire to move								
		away from claims-based reporting, we are								
		removing this measure from the PQRS								
0503/252	Effective Clinical Care	measure set.	ACEP	X	X					
0303/232	Effective Clinical Care	Anticoagulation for Acute Pulmonary Embolus Patients: Anticoagulation ordered	ACEP	Λ	Λ					
		for patients who have been discharged from								
		the emergency department (ED) with a								
		diagnosis of acute pulmonary embolus								
		Rationale: Measure lost Measure Owner support. Two commenters requested that CMS retain								
		this measure although it has lost measure								
		owner support and NQF endorsement. CMS								
		appreciates the commenters' desire to retain								
		this measure in the PQRS program and								
		encourages them to re-tool the measure as								
		needed and submit during the annual Call for								
		Measures for possible future inclusion.								
N/A/	Communication and	Surveillance after Endovascular	SVS		X					
256	Care Coordination	Abdominal Aortic Aneurysm Repair								
		(EVAR): Percentage of patients 18 years of								

NQF/ PQRS	NQS Domain	Measure Title and Description [‡]	Measure Steward	Claims	Registry	EHR	GPRO (Web	Measures	Groups Other Quality	Reporting	Programs
		age or older undergoing endovascular abdominal aortic aneurysm repair (EVAR) who have at least one follow-up imaging study after 3 months and within 15 months of EVAR placement that documents aneurysm sac diameter and endoleak status Rationale: Measure lost Measure Owner support.									
		CMS solicited but received no comments on this measure. Therefore, we are finalizing our proposal to retire this measure from PQRS beginning in 2014.									
0012/ 306	Community/Population Health	Prenatal Care: Screening for Human Immunodeficiency Virus (HIV): Percentage of patients, regardless of age, who gave birth during a 12-month period who were screened for HIV infection during the first or second prenatal visit Rationale: Deletion due to MU2 alignment.	AMA-PCPI			X				MU	1
		One commenter supported the removal of this measure as it has been retired from the									

NQF/ PQRS	NQS Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
		medical professional society's measure set. We appreciate the commenter's feedback and are not finalizing this measure for reporting under PQRS.							
0014/307	Patient Safety	Prenatal Care: Anti-D Immune Globulin: Percentage of D (Rh) negative, unsensitized patients, regardless of age, who gave birth during a 12-month period who received anti-D immune globulin at 26-30 weeks gestation Rationale: Deletion due to MU2 alignment. One commenter supported the removal of this measure as it has been retired from the medical professional society's measure set. We appreciate the commenter's feedback and are not finalizing this measure for reporting under PQRS.	AMA-PCPI			X			MU1
0027/ 308	Community/Population Health	Smoking and Tobacco Use Cessation, Medical Assistance: a. Advising Smokers and Tobacco Users to Quit, b. Discussing Smoking and Tobacco Use Cessation Medications, c. Discussing Smoking and Tobacco Use Cessation Strategies: Percentage of patients aged 18 years and	NCQA			X			MU1

NQF/ PQRS	NQS Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web	Measures	Groups Other Quality	Reporting	Programs
		older who were current smokers or tobacco users, who were seen by a practitioner during the measurement year and who received advice to quit smoking or tobacco use or whose practitioner recommended or discussed smoking or tobacco use cessation medications, methods or strategies Rationale: Deletion due to MU2 alignment. One commenter did not support the removal of this measure, stating it is an important measure in attempting to reduce tobacco usage. Another commenter was concerned tobacco cessation strategies would not be captured in existing smoking measures. We respectfully disagree and are therefore not finalizing this measure for inclusion in 2014 PQRS. We believe the tobacco cessation finalized in the PQRS measure set suffice to capture cessation consultation.									
0575/	Effective Clinical Care	Diabetes Mellitus: Hemoglobin A1c	NCQA			X			+		\dashv
313		Control (< 8%): The percentage of patients 18 through 75 years of age with a diagnosis	,								

NQF/ PQRS	NQS Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web	Measures	Groups Other Quality	Reporting Programs
		of diabetes (type 1 or type 2) who had HbA1c < 8%								
		Rationale: Deletion due to MU2 alignment.								
		One commenter was concerned with the								
		removal of this measure as it drives better								
		quality compared to PQRS measure #1 and it								
		has the potential to contribute to better								
		outcomes for patients with diabetes. Another								
		commenter requested the measure not be								
		retired as it provides different clinical information than PQRS measure #1 and that								
		alignment with other programs is not an								
		adequate reason for removal. We appreciate								
		the commenters' feedback but respectfully								
		disagree. It is our intention to align the								
		measures available for EHR-based reporting								
		under PQRS with the measures available for								
		reporting under the Medicare EHR Incentive								
		Program. Since this measure is not available								
		for reporting under the EHR Incentive								
		Program, we do not believe it is appropriate to include in the final PQRS measure set and								
		are therefore not finalizing for inclusion in								
		are increase not imanzing for incrusion in								

NQF/ PQRS	NQS Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web	Interface)" Measures	Groups Other Quality	Reporting Programs
		2014 PQRS.								
0493/321	Communication and Care Coordination	Participation by a Hospital, Physician or Other Clinician in a Systematic Clinical Database Registry that Includes Consensus Endorsed Quality: Participation in a systematic qualified clinical database registry involves: a. Physician or other clinician submits standardized data elements to registry. b. Data elements are applicable to consensus endorsed quality measures. c. Registry measures shall include at least two (2) representative NQF consensus endorsed measures for registry's clinical topic(s) and report on all patients eligible for the selected measures. d. Registry provides calculated measures results, benchmarking, and quality improvement information to individual physicians and clinicians. e. Registry must receive data from more than 5 separate practices and may not be located (warehoused) at an individual group's practice. Participation in a national or statewide registry is encouraged for this measure.	OFMQ	X	X					

NQF/ PQRS	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web	Measures	Groups Other Quality	Reporting	Programs
		f. Registry may provide feedback directly to the provider's local registry if one exists.									
		Rationale: Due we believe participation in a clinical data registry is best captured under the new qualified clinical data registry option, CMS no longer believes this measure is necessary to report and is therefore proposing to remove this measure.									
		We received several comments opposing the removal of this measure due to the implementation of Qualified Clinical Data Registries, stating they believe it is premature and that the measure is an important bridge to increased registry-based									
		PQRS reporting. The commenters urged CMS to postpone the elimination of this measure until it has a better understanding of how many registries will be able to fulfill the new Qualified Clinical Data Registry option as proposed. We appreciate the commenters' feedback, but we are not retaining this measure for reporting under PQRS.									
N/A/N/A	Communication and	Total Knee Replacement: Coordination of	AAHKS/AMA-					X			

NQF/ PQRS	NQS Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web	Measures	Groups Other Quality	Reporting	Programs
	Care Coordination	Post Discharge Care: Percentage of patients undergoing total knee replacement who received written instructions for post discharge care including all the following: post discharge physical therapy, home health care, post discharge deep vein thrombosis (DVT) prophylaxis and follow-up physician visits	PCPI								
		Rationale: Measure Owner decision to remove this measure from Total Knee Replacement and replace with the measure: Shared Decision-Making: Trial of Conservative (Non-surgical) Therapy									
		CMS solicited but received no comments on this measure. Therefore, we are finalizing our proposal to retire this measure from PQRS beginning in 2014.									
N/A/N/A	Person and Caregiver- Centered Experience and Outcomes	Chronic Wound Care: Patient Education Regarding Long-Term Compression Therapy: Percentage of patients aged 18 years and older with a diagnosis of venous ulcer who received education regarding the need for long term compression therapy	AMA-PCPI	X	X						

NQF/ PQRS	NQS Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web	Measures	Groups Other Quality	Reporting	Programs
		including interval replacement of compression stockings within the 12 month reporting period									
		Rationale: This measure concept is routinely met in a clinical setting. CMS believes it would not indicate a true quality outcome.									
		Two commenters felt this measure adds an important aspect of care related to the two chronic wound care measures currently in the									
		PQRS program. CMS appreciates the commenters' feedback but as indicated in our rationale, do not believe it would indicate a true quality outcome. For this reason, we are									
N/A/N/A	Effective Clinical Care	not finalizing for inclusion in PQRS. Osteoporosis: Status of Participation in Weight-Bearing Exercise and Weight-	ABIM					X			_
		bearing Exercise Advice: Percentage of patients aged 18 and older with a diagnosis of osteoporosis, osteopenia, or prior low impact fracture; women age 65 and older; or men age 70 and older whose status regarding participation in weight-bearing exercise was documented and for those not participating									

NQF/ PQRS	NQS Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures	Other Quality Reporting	Programs
		regularly who received advice within 12 months to participate in weight-bearing exercise								
		Rationale: This measures group was deleted due to the amount of measures that had duplicative medical concepts within the PQRS program.								
		Several commenters opposed the deletion of all measures originally proposed to comprise the Osteoporosis measures group. Commenters recommended the implementation of a revised Osteoporosis measures group utilizing six existing PQRS measures. We appreciate the commenters' feedback but note, the suggested measures have not been analyzed to determine the feasibility of reporting these measures together within a measures group. Therefore, we are finalizing our proposal to remove the								
N/A/N/A	Effective Clinical Care	Osteporosis: Current Level of Alcohol	ABIM					X		
		Use and Advice on Potentially Hazardous Drinking Prevention: Percentage of patients								

NQF/ PQRS	NQS Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web	Interface)*	Groups	Other Quality	Keporting Programs	Livelanis
		aged 18 and older with a diagnosis of osteoporosis, osteopenia, or prior low impact fracture; women age 65 and older; or men age 70 and older whose current level of alcohol use was documented and for those engaging in potentially hazardous drinking who received counseling within 12 months Rationale: This measures group was deleted due to the amount of measures that had duplicative medical concepts within the PQRS program. Several commenters opposed the deletion of all measures originally proposed to comprise the Osteoporosis measures group. Commenters recommended the implementation of a revised Osteoporosis measures group utilizing six existing PQRS measures. We appreciate the commenters' feedback but note, the suggested measures have not been analyzed to determine the feasibility of reporting these measures together within a measures group. Therefore, we are finalizing our proposal to remove the										

NQF/ PQRS	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web	Interface)*	Measures Groups	Other Quality	Reporting	Programs
		Osteporosis measures group from PQRS.										
N/A/N/A	Patient Safety	Osteoporosis: Screen for Falls Risk Evaluation and Complete Falls Risk Assessment and Plan of Care: Percentage of patients aged 18 and older with a diagnosis of osteoporosis, osteopenia, or prior low impact fracture; women age 65 and older; or men age 70 and older who had a screen for falls risk evaluation within the past 12 months and for those reported as having a history of two or more falls, or fall-related injury who had a complete risk assessment for falls and a falls plan of care within the past 12 months Rationale: This measures group was deleted due to the amount of measures that had duplicative medical concepts within the PQRS program. Several commenters opposed the deletion of all measures originally proposed to comprise the Osteoporosis measures group. Commenters recommended the implementation of a revised Osteoporosis	ABIM						X			

NQF/ PQRS	NQS Domain	Measure Title and Description [‡]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures	Other Quality	Reporting	Programs
N/A/N/A	Effective Clinical Care	measures group utilizing six existing PQRS measures. We appreciate the commenters' feedback but note, the suggested measures have not been analyzed to determine the feasibility of reporting these measures together within a measures group. Therefore, we are finalizing our proposal to remove the Osteporosis measures group from PQRS. Osteoporosis: Dual-Emission X-ray	ABIM					X			
1071071	Directive Chimeur Care	Absorptiometry (DXA) Scan: Percentage of patients aged 18 and older with a diagnosis of osteoporosis, osteopenia, or prior low impact fracture; women age 65 and older; or men age 70 and older who had a DXA scan and result documented						7			
		Rationale: This measures group was deleted due to the amount of measures that had duplicative medical concepts within the PQRS program. Several commenters opposed the deletion of all measures originally proposed to comprise the Osteoporosis measures group. Commenters recommended the									

NQF/ PQRS	NQS Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures	Groups Other Quality	Reporting	Programs
		implementation of a revised Osteoporosis measures group utilizing six existing PQRS measures. We appreciate the commenters' feedback but note, the suggested measures have not been analyzed to determine the feasibility of reporting these measures together within a measures group. Therefore, we are finalizing our proposal to remove the Osteoporosis measures group from PQRS.									
N/A/N/A	Effective Clinical Care	Osteoporosis: Calcium Intake Assessment and Counseling: Percentage of patients aged 18 and older with a diagnosis of osteoporosis, osteopenia, or prior low impact fracture; women age 65 and older; or men age 70 and older who had calcium intake assessment and counseling at least once within 12 months Rationale: This measures group was deleted due to the amount of measures that had duplicative medical concepts within the PQRS program. Several commenters opposed the deletion of all measures originally proposed to comprise	ABIM					X			

NQF/ PQRS	NQS Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web	Measures	Groups Other Quality	Reporting	Programs
N/A/N/A	Effective Clinical Care	the Osteoporosis measures group. Commenters recommended the implementation of a revised Osteoporosis measures group utilizing six existing PQRS measures. We appreciate the commenters' feedback but note, the suggested measures have not been analyzed to determine the feasibility of reporting these measures together within a measures group. Therefore, we are finalizing our proposal to remove the Osteoporosis measures group from PQRS. Osteoporosis: Vitamin D Intake Assessment and Counseling: Percentage of patients aged 18 and older with a diagnosis of osteoporosis, osteopenia, or prior low impact fracture; women age 65 and older; or men age 70 and older who had vitamin D intake assessment and counseling at least once within 12 months Rationale: This measures group was deleted due to the amount of measures that had duplicative medical concepts within the PQRS program.	ABIM					X			

NQF/ PQRS	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web	Interface)*	Measures Groups	Other Quality	Reporting	Programs
		Several commenters opposed the deletion of all measures originally proposed to comprise the Osteoporosis measures group. Commenters recommended the implementation of a revised Osteoporosis measures group utilizing six existing PQRS measures. We appreciate the commenters' feedback but note, the suggested measures have not been analyzed to determine the feasibility of reporting these measures together within a measures group. Therefore, we are finalizing our proposal to remove the Osteoporosis measures group from PQRS.										
N/A/N/A	Effective Clinical Care	Osteoporosis: Pharmacologic Therapy: Percentage of patients aged 18 and older with a diagnosis of osteoporosis, osteopenia, or prior low impact fracture; women age 65 and older; or men age 70 and older who were prescribed pharmacologic therapy approved by the Food and Drug Administration Rationale: This measures group was deleted due to the amount of measures that had duplicative medical concepts within the PQRS program.	ABIM						X			

NQF/ PQRS	NQS Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web	Measures	Groups Other Onality	Reporting	Programs
		Several commenters opposed the deletion of all measures originally proposed to comprise the Osteoporosis measures group. Commenters recommended the implementation of a revised Osteoporosis measures group utilizing six existing PQRS measures. We appreciate the commenters' feedback but note, the suggested measures have not been analyzed to determine the feasibility of reporting these measures together within a measures group. Therefore, we are finalizing our proposal to remove the Osteoporosis measures group from PQRS.									
N/A/N/A	Effective Clinical Care	Preventive Cardiology Composite: Blood Pressure at Goal: Percentage of patients in the sample whose most recent blood pressure reading was at goal Rationale: This measures group was deleted due to the amount of measures that had duplicative medical concepts within the PQRS program. One commenter opposed the deletion of all	ABIM					X			

NQF/ PQRS	NQS Domain	Measure Title and Description[‡]	Measure Steward	Claims	Registry	EHR	GPRO (Web	Measures	Groups	Reporting	Programs
		measures originally proposed to comprise the Preventive Cardiology measures group, disagreeing with CMS' opinion that this measures group is duplicative of other measures. Specifically, the commenter's concern was that existing PQRS measures only address aspirin use among patients diagnosed with specific heart conditions. We appreciate the commenter's feedback, but we are not retaining the Preventive Cardiology measures group for reporting under PQRS.									
N/A/N/A	Effective Clinical Care	Preventive Cardiology Composite: Low Density Lipids (LDL) Cholesterol at Goal: Percentage of patients in the sample whose LDL cholesterol is considered to be at goal, based upon their coronary heart disease (CHD) risk factors Rationale: This measures group was deleted due to the amount of measures that had duplicative medical concepts within the PQRS program. One commenter opposed the deletion of all measures originally proposed to comprise the	ABIM					2			

NQF/ PQRS	NQS Domain	Measure Title and Description [‡]	Measure Steward	Claims	Registry	EHR	GPRO (Web	Measures	Groups	Reporting	Programs
		Preventive Cardiology measures group, disagreeing with CMS' opinion that this measures group is duplicative of other measures. Specifically, the commenter's concern was that existing PQRS measures only address aspirin use among patients diagnosed with specific heart conditions. We appreciate the commenter's feedback, but we are not retaining the Preventive Cardiology measures group for reporting under PQRS.									
N/A/N/A	Effective Clinical Care	Preventive Cardiology Composite: Timing of Lipid Testing Complies with Guidelines: Percentage of patients in the sample whose timing of lipid testing complies with guidelines (lipid testing performed in the preceding 12-month period (with a three-month grace period) for patients with known coronary heart disease (CHD) or CHD risk equivalent (prior myocardial infarction (MI), other clinical CHD, symptomatic carotid artery disease, peripheral artery disease, abdominal aortic aneurysm, diabetes mellitus); or in the preceding 24-month period (with a three-month grace period) for patients with ≥ 2 risk	ABIM					X			

NQF/ PQRS	NQS Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web	Measures	Groups Other Quality	Reporting Programs
		factors for CHD (smoking, hypertension, low high density lipid (HDL), men \geq 45 years, women \geq 55 years, family history of premature CHD; HDL \geq 60 mg/dL acts as a negative risk factor); or in the preceding 60-month period (with a three-month grace period) for patients with \leq 1 risk factor for CHD)								
		Rationale: This measures group was deleted due to the amount of measures that had duplicative medical concepts within the PQRS program.								
		One commenter opposed the deletion of all measures originally proposed to comprise the Preventive Cardiology measures group, disagreeing with CMS' opinion that this measures group is duplicative of other measures. Specifically, the commenter's concern was that existing PQRS measures only address aspirin use among patients diagnosed with specific heart conditions.								
		We appreciate the commenter's feedback,								

NQF/ PQRS	NQS Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures	Other Quality	Keporting Programs
		but, based on the rationale stated above, we are not retaining the Preventive Cardiology measures group for reporting under PQRS.								
N/A/N/A	Effective Clinical Care	Preventive Cardiology Composite: Diabetes Documentation or Screen Test: Percentage of patients in the sample who had a screening test for type 2 diabetes or had a diagnosis of diabetes Rationale: This measures group was deleted due to the amount of measures that had duplicative medical concepts within the PQRS program. One commenter opposed the removal of this measure because they believe it has potential to contribute to better outcomes for patients with diabetes. Another commenter opposed the deletion of all measures originally proposed to comprise the Preventive Cardiology measures group, disagreeing with CMS' opinion that this measures group is duplicative of other measures. Specifically, the commenter's concern was that existing PQRS measures only address aspirin use	ABIM					X		

NQF/ PQRS	NQS Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
		among patients diagnosed with specific heart conditions. We appreciate the commenter's feedback, but we are not retaining the Preventive Cardiology measures group for reporting under PQRS.							
N/A/N/A	Effective Clinical Care	Preventive Cardiology Composite: Counseling for Diet and Physical Activity: Percentage of patients who received dietary and physical activity counseling Rationale: This measures group was deleted due to the amount of measures that had duplicative medical concepts within the PQRS program. One commenter opposed the deletion of all measures originally proposed to comprise the Preventive Cardiology measures group, disagreeing with CMS' opinion that this measures group is duplicative of other measures. Specifically, the commenter's concern was that existing PQRS measures only address aspirin use among patients diagnosed with specific heart conditions. We appreciate the commenter's feedback, but we	ABIM					X	

NQF/ PQRS	NQS Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures	Groups Other Quality	Reporting Programs
		are not retaining the Preventive Cardiology measures group for reporting under PQRS.								
N/A/N/A	Effective Clinical Care	Duayantiya Candialagy Commonita	ABIM					X		
IN/A/IN/A	Effective Chinical Care	Preventive Cardiology Composite: Correct Determination of Ten-Year Risk for Coronary Death or Myocardial Infarction (MI): Number of patients in the sample whose ten-year risk of coronary death or MI is correctly assessed and documented Rationale: This measures group was deleted due to the amount of measures that had duplicative medical concepts within the PQRS program. One commenter opposed the deletion of all measures originally proposed to comprise the Preventive Cardiology measures group, disagreeing with CMS' opinion that this measures group is duplicative of other measures. Specifically, the commenter's concern was that existing PQRS measures only address aspirin use among patients	ADIM							

NQF/ PQRS	NQS Domain	Measure Title and Description [‡]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures	Other Quality	Reporting	Frograms
		diagnosed with specific heart conditions. We									
		appreciate the commenter's feedback, but we									
		are not retaining the Preventive Cardiology									
		measures group for reporting under PQRS.									
N/A/N/A	Effective Clinical Care	Preventive Cardiology Composite:	ABIM					X			
		Appropriate Use of Aspirin or Other									
		Antiplatelet/Anticoagulant Therapy:									
		Percentage of patients in the sample who are:									
		1) taking aspirin or other									
		anticoagulant/antiplatelet therapy, or 2)									
		under age 30, or 3) age 30 or older and who									
		are documented to be at low risk. Low-risk									
		patients include those who are documented									
		with no prior coronary heart disease (CHD)									
		or CHD risk equivalent (prior myocardial									
		infarction (MI), other clinical CHD,									
		symptomatic carotid artery disease,									
		peripheral artery disease, abdominal aortic									
		aneurysm, diabetes mellitus) and whose ten-									
		year risk of developing CHD is < 10%									
		Rationale: This measures group was deleted									
		due to the amount of measures that had									
		duplicative medical concepts within the									
		PQRS program.									

NQF/ PQRS	NQS Domain	Measure Title and Description ⁴	Measure Steward	Claims	Registry	EHR	GPRO (Web	Interface)* Measures	Groups	Other Quality	Keporting December	Programs
		One commenter opposed the deletion of all measures originally proposed to comprise the Preventive Cardiology measures group, disagreeing with CMS' opinion that this measures group is duplicative of other measures. Specifically, the commenter's concern was that existing PQRS measures only address aspirin use among patients diagnosed with specific heart conditions. We appreciate the commenter's feedback, but we are not retaining the Preventive Cardiology measures group for reporting under PQRS.										
N/A/N/A	Effective Clinical Care	Preventive Cardiology Composite: Smoking Status and Cessation Support: Percentage of patients in the sample whose current smoking status is documented in the chart, and if they were smokers, were documented to have received smoking cessation counseling during the reporting period Rationale: This measures group was deleted due to the amount of measures that had duplicative medical concepts within the	ABIM						X			

NQF/ PQRS	NQS Domain	Measure Title and Description [¥]	Measure Steward	Claims	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting	Programs
		PQRS program. One commenter opposed the deletion of all measures originally proposed to comprise the Preventive Cardiology measures group, disagreeing with CMS' opinion that this measures group is duplicative of other measures. Specifically, the commenter's concern was that existing PQRS measures only address aspirin use among patients diagnosed with specific heart conditions. We appreciate the commenter's feedback, but we are not retaining the Preventive Cardiology measures group for reporting under PQRS.								

[¥] Measure details including titles, descriptions and measure owner information may vary during a particular program year. This is due to the timing of measure specification preparation and the measure versions used by the various reporting options/methods. Please refer to the measure specifications that apply for each of the reporting options/methods for specific measure details.

b. PQRS Measures Groups

Section 414.90(b) defines a measures group as "a subset of four or more Physician Quality Reporting System measures that have a particular clinical condition or focus in common. The denominator definition and coding of the measures group identifies the condition or focus that is shared across the measures within a particular measures group."

In the CY 2014 PFS proposed rule, we proposed (78 FR 43448) to modify the minimum amount of measures that may be included in a PQRS measures group from four to six (78 FR 43448). Therefore, we proposed (78 FR 43448) to modify the definition of a measures group at §414.90(b) to indicate that a measures group would consist of at least six measures. Consequently, we proposed (78 FR 43448) to add additional measures to each measures group that previously contained less than six measures (see Tables 31 through 56 at 78 FR 43449 through 43474). We solicited and received the following public comments on these proposals:

Comment: Several commenters did not support our proposal to modify the definition of a measures group at §414.90(b) to indicate that a measures group would consist of at least six measures. Commenters believed that the proposal to increase the minimum number of measures in a measures group from four to six measures seemed arbitrary. Some of these commenters suggested that the measures CMS proposed to add to measures groups that previously contained less than six measures were not appropriate to these measures groups as they did not address the specific clinical topic or condition addressed in the measures groups.

Response: We understand the commenters' concerns regarding this proposal. Although we still plan to increase the minimum number of measures in a measures group in the future, we are not finalizing this proposal at this time. As such, we are not finalizing our proposals to add additional measures to measures groups that previously contained less than six measures. We will work with the measure developers and owners of these measures groups to appropriately add measures to measures groups that only contain four measures within the measures group.

In addition, we solicited and received the following comment on our specific proposed measures groups:

<u>Comment:</u> Chronic Kidney Disease Measures Group - One commenter supported all proposed measures in the Chronic Kidney Disease (CKD) measures group as they represent important aspects of care that can delay CKD progression and protect patients from adverse outcomes.

Response: Since we are not finalizing the proposal to increase the number of measures in a measures group from four to six, the Chronic Kidney Disease (CKD) measures group will remain as it was finalized in 2013. Therefore, we are not including PQRS measure # 130: Documentation of Current Medications in the Medical Record and PQRS measure #226: Preventive Care and Screening: Tobacco use: Screening and Cessation Intervention, in the measures group as proposed.

<u>Comment:</u> Hypertension Measures Group - One commenter agrees with the Hypertension measures group but recommends replacing PQRS measure #300 Hypertension: Blood Pressure Control, with PQRS measure #236 Hypertension: Controlling High Blood Pressure, citing the reason of the expanded age range to 90 as inconsistent and creating confusion.

Response: We appreciate the commenters' feedback. However, we note that the age range of all of the measures within the Hypertension measures group is 18 through 90, and the existing measures have been examined to determine the ability to report and analyze the measures contained within the measures group as a whole, whereas the suggested PQRS measure has not been analyzed to determine the feasibility of reporting these measures together within a measures group.

<u>Comment</u>: Another commenter showed support for screening for chronic kidney disease in people with hypertension, but recommended replacing PQRS measure #297 Hypertension: Urine Protein Test and PQRS measure #298 Hypertension: Annual Serum Creatinine Test with a measure of documented eGFR and urine albumin-creatinine ration.

Response: CMS appreciates the commenters' suggestions, but as the suggested changes to the measures group have not been analyzed, nor were they included in the CY2014 PFS proposed rule, CMS

is retaining the Hypertension measures group as it was finalized in the CY 2013 PFS final rule (77 FR 69272).

<u>Comment</u>: Cataracts Measures Group - Two commenters expressed concern with the proposed inclusion of Patient-Centered Surgical Risk Assessment and Communication in the Cataracts measures group, stating that this measure is not reportable for cataract surgeons.

Response: Since we are not finalizing the proposal to increase the number of measures in a measures group from four to six, we are retaining the composition of the Cataracts measures group for 2014 as it was finalized in the CY 2013 PFS final rule (77 FR 69272). Therefore, we are not including PQRS measure # 130: Documentation of Current Medications in the Medical Record, PQRS measure #226: Preventive Care and Screening: Tobacco use: Screening and Cessation Intervention, and Patient-Centered Surgical Risk Assessment and Communication in the measures group as proposed.

Comment: Sleep Apnea Measures Group - Several commenters support the Sleep Apnea measures group. There was however, concern regarding the addition of PQRS measures #128: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up, # 130: Documentation of Current Medications in the Medical Record, and #226: Preventive Care and Screening: Tobacco use: Screening and Cessation Intervention.

Response: Since we are not finalizing the proposal to increase the number of measures in a measures group from four to six, we are retaining the Sleep Apnea measures group for 2014 as it was finalized in CY 2013 PFS final rule (77 FR 69272). Therefore, we are not including PQRS measures #128, #130 and #226 in the measures group as proposed.

<u>Comment</u>: Dementia Measures Group - Several commenters expressed support for the retention of the Dementia measures group. One commenter urged that even though the measures are not NQF-endorsed they are retained for continued use in PQRS and other agency programs. One commenter did suggest the inclusion of three additional measures: (1) a measure that requires physicians to assess cognitive impairment using a standardized assessment tool; (2) a measure that requires documentation of

a diagnosis in the medical record; and (3) the American Medical Association's (AMA) dementia performance measure on palliative care counseling and advance care planning.

Response: CMS appreciates the suggestions, however as previously stated, the existing measures have been examined to determine the ability to report and analyze the measures contained within the measures group as a whole, whereas the suggested measured have not been analyzed to determine the feasibility of reporting these measures together within a measures group. Additionally, the suggested measures were not included in the CY2014 PFS proposed rule. Therefore, CMS is retaining the Dementia measures group as it was finalized in the CY 2013 PFS final rule (77 FR 69272).

<u>Comment</u>: Perioperative Care Measures Group - Two commenters expressed concern with the proposed inclusion of the following measures in the Perioperative Care measures group: Patient-Centered Surgical Risk Assessment and Communication, PQRS measure # 130: Documentation of Current Medications in the Medical Record and PQRS measure #226: Preventive Care and Screening: Tobacco use: Screening and Cessation Intervention.

Response: Since we are not finalizing the proposal to increase the number of measures in a measures group from four to six, we are retaining the Perioperative Care measures group for 2014 as it was finalized in CY 2013 PFS final rule (77 FR 69272). Therefore, we are not including Patient-Centered Surgical Risk Assessment and Communication, PQRS #130 and PQRS #226 in the measures group as proposed.

Comment: Ischemic Vascular Disease Measures Group - One commenter recommended not removing PQRS measure #201: Ischemic Vascular Disease (IVD): Blood Pressure Management from the IVD measures group without adding a measure focused on people with IVD. CMS appreciates the commenters' suggestions, but disagrees due to CMS' efforts to reduce duplicity in measures and the fact that this measure was not proposed for inclusion in the CY2014 PFS proposed rule. One commenter agreed with the CMS proposal to revise the Ischemic Vascular Disease measures group to include additional quality measures. CMS appreciates the commenters' support, but is not finalizing the proposal to increase the number of measures in a measures group from four to six.

Response: CMS is finalizing the Ischemic Vascular Disease measures group as it was finalized in CY 2013 PFS final rule (77 FR 69272), without PQRS measures #128: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up and #130: Documentation of Current Medications in the Medical Record.

Comment: Asthma Measures Group - One commenter noted that the Asthma measures group is an important measures group that is of interest to the pulmonary, critical care and sleep provider community. One commenter expressed concern with the inclusion of PQRS measures #110: Preventive Care and Screening: Influenza Immunization and #130: Documentation of Current Medications in the Medical Record, stating concern that is will create additional confusion for providers reporting on the measure group.

Response: Since we are not finalizing the proposal to increase the number of measures in a measures group from four to six, we are retaining the Asthma measures group for 2014 as it was finalized in CY 2013 PFS final rule (77 FR 69272) and not including PQRS #110 and PQRS #130 in the measures group as proposed.

<u>Comment</u>: Chronic Obstructive Pulmonary Disease (COPD) Measures Group - One commenter noted that the COPD measures group is an important measures group that is of interest to the pulmonary, critical care and sleep provider community.

Response: Since we are not finalizing the proposal to increase the number of measures in a measures group from four to six, we are retaining the COPD measures group for 2014 as it was finalized in CY 2013 PFS final rule (77 FR 69272) and not including PQRS #130 in the measures group as proposed.

<u>Comment</u>: Total Knee Replacement Measures Group - One commenter expressed support for the Total Knee Replacement measures group, including PQRS measures #130: Documentation of Current Medications in the Medical Record and #226: Preventive Care and Screening: Tobacco use: Screening and Cessation Intervention. They did suggest that in future year's measure #226 be replaced with a

measure similar to the functional status assessment for knee replacement measure finalized in the EHR Incentive Program Stage 2 Final Rule. CMS appreciates the commenters' suggestion.

Response: Since we are not finalizing the proposal to increase the number of measures in a measures group from four to six, we are retaining the Total Knee Replacement measures group for 2014 as finalized in the CY 2013 PFS final rule (77 FR 69272), without PQRS #130 and PQRS #226 in the measures group as proposed.

<u>Comment</u>: General Surgery Measures Group - We received several comments supporting the inclusion of a General Surgery measures group.

Response: Based on comments received and the decision to not finalize the proposal to increase the number of measures in a measures group from four to six, we are finalizing the General Surgery measures group for 2014, and not including PQRS measure # 130: Documentation of Current Medications in the Medical Record, PQRS measure #226: Preventive Care in the measures group as proposed. Additionally, CMS has decided to combine the proposed Gastrointestinal Surgery measures group with the General Surgery measures group to decrease reporting burden on eligible professionals. The Iatrogenic Injury to Adjacent Organ/Structure measure proposed for the General Surgery and Gastrointestinal Surgery measures groups is not being finalized.

Comment: Optimizing Patient Exposure to Ionizing Radiation Measures Group – Several commenters expressed support for this measures group, stating it will allow for more reporting opportunities for radiologists and will encourage physicians to monitor and consider prior radiation exposure, in an effort to reduce unnecessary radiation exposure to Medicare beneficiaries. One commenter agreed with the intent of the measures group but questioned the inclusion of the following measure: Count of Potential High Dose Radiation Imaging Studies, and suggested replacing it with three existing PQRS measures: #322 Cardiac Stress Imaging Not Meeting Appropriate Use Criteria:

Preoperative Evaluation in Low-Risk Surgery Patients, #323 Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Routine Testing After Percutaneous Coronary Intervention (PCI) and #324 Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Testing in Asymptomatic, Low-Risk

Patients. CMS appreciates the commenters' suggestions, but since we did not propose including these measures as part of the measures group in the CY2014 PFS Proposed Rule, we are not addressing these comments in this final rule. We received several comments supporting the Optimizing Patient Exposure to Ionizing Radiation Measures Group in general; however they encouraged CMS to finalize this measures group only after the individual measures have received NQF endorsement.

Response: While we appreciate the commenters' feedback, we believe there are circumstances (such as when a measure addresses a gap in the PQRS measure set) where we may believe that it is important to include a non-NQF endorsed measure to be available for reporting under PQRS. Section 1848(k) (2) (C) (ii) of the Act authorizes the Secretary to include measures available for reporting under PQRS that are not NQF endorsed. Therefore, we are finalizing the Optimizing Patient Exposure to Ionizing Radiation measures group with all of the proposed component measures for 2014.

<u>Comment</u>: Diabetes Measures Group - One commenter recommended not removing PQRS measure #3: Diabetes Mellitus: High Blood Pressure Control from the Diabetes measures group without adding a measure focused on blood pressure control for people with Diabetes.

Response: CMS appreciates the commenters' suggestions, but disagrees due to CMS' efforts to reduce duplicity in measures and the fact that this measure was not proposed for inclusion in the CY2014 PFS proposed rule. Additionally, CMS is not finalizing the proposal to increase the number of measures in a measures group from four to six. Therefore, CMS is finalizing the Diabetes measures group without PQRS measure #130: Documentation of Current Medications in the Medical Record.

The following measures groups received no public comments:

- Back Pain Measures Group measures #130 and #131 will not be finalized for inclusion in this measures group as proposed.
- Hepatitis C Measures Group measures #130 and #226 will not be finalized for inclusion in this measures group as proposed.
- Heart Failure Measures Group measures #128 and #130 will not be finalized for inclusion in this measures group as proposed.

• Coronary Artery Disease (CAD) Measures Group - measures #128 and #130 will not be finalized for inclusion in this measures group as proposed.

- HIV/AIDS Measures Group measure #130 will not be finalized for inclusion in this measures group as proposed.
 - Inflammatory Bowel Disease Measures Group this measures group is finalized as proposed.
 - Cardiovascular Prevention Measures Group this measures group is finalized as proposed.
 - Oncology Measures Group this measures group is finalized as proposed.
 - Preventive Care Measures Group this measures group is finalized as proposed.
- Coronary Artery Bypass Graft Measures Group (CABG) this measures group is finalized as proposed.
 - Rheumatoid Arthritis (RA) Measures Group this measures group is finalized as proposed.

Tables 55 through 79 specify the final measures groups that are reportable for the PQRS for 2014 and beyond. Please note that, as we are not finalizing our proposal to modify the definition of a measures group to require that a measures group contain at least 6 measures, the measures groups we finalized in the CY 2013 PFS final rule (77 FR 69272) will remain unchanged. Please note that, since we are finalizing our proposal to eliminate the reporting of measures groups via claims, all measures groups in the 2014 Physician Quality Reporting System are reportable through registry-based reporting only.

¥ Measure details including titles, descriptions and measure owner information may vary during a particular program year. This is due to the timing of measure specification preparation and the measure versions used by the various reporting options/methods. Please refer to the measure specifications that apply for each of the reporting options/methods for specific measure details.

TABLE 55: Diabetes Mellitus Measures Group

NQF/ PQRS	Measure Title and Description	Measure Developer
0059/	Diabetes: Hemoglobin A1c Poor Control: Percentage of patients 18-75 years of age	NCQA
1	with diabetes who had hemoglobin $A1c > 9.0\%$ during the measurement period	
0064/	Diabetes: Low Density Lipoprotein (LDL-C) Control (< 100 mg/dL): Percentage of	NCQA
2	patients 18-75 years of age with diabetes whose LDL-C was adequately controlled (<	
	100 mg/dL) during the measurement period	

0055/	Diabetes: Eye Exam: Percentage of patients 18 through 75 years of age with a diagnosis	NCQA
117	of diabetes (type 1 and type 2) who had a retinal or dilated eye exam in the measurement	
	period or a negative retinal or dilated eye exam (negative for retinopathy) in the year	
	prior to the measurement period	
0062/	Diabetes: Medical Attention for Nephropathy: The percentage of patients 18-75 years	NCQA
119	of age with diabetes who had a nephropathy screening test or evidence of nephropathy	
	during the measurement period	
0056/	Diabetes: Foot Exam: Percentage of patients aged 18-75 years of age with diabetes who	NCQA
163	had a foot exam during the measurement period	

Finalized in the CY 2013 PFS final rule (see Table 97 at 77 FR 69273).

TABLE 56: Chronic Kidney Disease (CKD) Measures Group

NQF/ PQRS	Measure Title and Description	Measure Developer
0041/	Preventive Care and Screening: Influenza Immunization: Percentage of patients	AMA-PCPI
110	aged 6 months and older seen for a visit between October 1 and March 31 who	
	received an influenza immunization OR who reported previous receipt of an influenza	
	immunization	
1668/	Adult Kidney Disease: Laboratory Testing (Lipid Profile): Percentage of patients	AMA-PCPI
121	aged 18 years and older with a diagnosis of chronic kidney disease (CKD) (stage 3, 4,	
	or 5, not receiving Renal Replacement Therapy [RRT]) who had a fasting lipid profile	
	performed at least once within a 12-month period	
AQA	Adult Kidney Disease: Blood Pressure Management: Percentage of patient visits	AMA-PCPI
adopted/122	for those patients aged 18 years and older with a diagnosis of chronic kidney disease	
	(CKD) (stage 3, 4, or 5, not receiving Renal Replacement Therapy [RRT]) and	
	proteinuria with a blood pressure $< 130/80$ mmHg OR $\ge 130/80$ mmHg with a	
	documented plan of care	
1666/	Adult Kidney Disease: Patients On Erythropoiesis-Stimulating Agent (ESA) -	AMA-PCPI
123	Hemoglobin Level > 12.0 g/dL: Percentage of calendar months within a 12-month	
	period during which a hemoglobin level is measured for patients aged 18 years and	
	older with a diagnosis of advanced chronic kidney disease (CKD) (stage 4 or 5, not	
	receiving Renal Replacement Therapy [RRT]) or End Stage Renal Disease (ESRD)	
	(who are on hemodialysis or peritoneal dialysis) who are also receiving	
	erythropoiesis-stimulating agent (ESA) therapy have a hemoglobin level > 12.0 g/dL	

Finalized in the CY 2013 PFS final rule (see Table 98 at 77 FR 69273).

TABLE 57: Preventive Care Measures Group

NQF/ PQRS	Measure Title and Description	Measure Developer
0046/	Screening or Therapy for Osteoporosis for Women Aged 65 Years and Older:	AMA-PCPI/
39	Percentage of female patients aged 65 years and older who have a central dual-energy	NCQA
	X- ray absorptiometry (DXA) measurement ordered or performed at least once since	
	age 60 or pharmacologic therapy prescribed within 12 months	
0098/	Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence	AMA-PCPI/
48	in Women Aged 65 Years and Older: Percentage of female patients aged 65 years and	NCQA
	older who were assessed for the presence or absence of urinary incontinence within 12	
	months	

0041/	Preventive Care and Screening: Influenza Immunization: Percentage of patients	AMA-PCPI
110	aged 6 months and older seen for a visit between October 1 and March 31 who received	
	an influenza immunization OR who reported previous receipt of an influenza	
	immunization	
0043/	Pneumonia Vaccination Status for Older Adults: Percentage of patients 65 years of	NCQA
111	age and older who have ever received a pneumococcal vaccine	
N/A/	Breast Cancer Screening: Percentage of women 50 through 74 years of age who had a	NCQA
112	mammogram to screen for breast cancer within 27 months	
0034/	Colorectal Cancer Screening: Percentage of patients 50 through 75 years of age who	NCQA
113	had appropriate screening for colorectal cancer	
0421/	Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-	CMS
128	Up: Percentage of patients aged 18 years and older with a documented BMI during the	
	current encounter or during the previous 6 months AND when the BMI is <u>outside of</u>	
	normal parameters , a follow-up plan is documented during the encounter or during the previous 6 months of the encounter	
	Normal Parameters: Age 65 years and older BMI \geq 23 and \leq 30; Age 18 – 64 years	
	BMI \geq 18.5 and \leq 25	
AQA	Preventive Care and Screening: Unhealthy Alcohol Use – Screening: Percentage of	AMA-PCPI
Adopted/	patients aged 18 years and older who were screened for unhealthy alcohol use using a	7111171 1 01 1
173	systematic screening method within 24 months	
0028/	Preventive Care and Screening: Tobacco Use: Screening and Cessation	AMA-PCPI
226	Intervention: Percentage of patients 18 years and older who were screened for tobacco	7.1.111.1.011
220	use one or more times within 24 months AND who received cessation counseling	
	intervention if identified as a tobacco user	
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Finalized in the CY 2013 PFS final rule (see Table 99 at 77 FR 69273).

TABLE 58: Coronary Artery Bypass Graft (CABG) Measures Group

NQF/ PQRS	Measure Title and Description	Measure Developer
0134/	Coronary Artery Bypass Graft (CABG): Use of Internal Mammary Artery (IMA)	STS
43	in Patients with Isolated CABG Surgery: Percentage of patients aged 18 years and	
	older undergoing isolated CABG surgery who received an IMA graft	
0236/	Coronary Artery Bypass Graft (CABG): Preoperative Beta-Blocker in Patients	CMS
44	with Isolated CABG Surgery: Percentage of isolated Coronary Artery Bypass Graft	
	(CABG) surgeries for patients aged 18 years and older who received a beta-blocker	
	within 24 hours prior to surgical incision	
0129/	Coronary Artery Bypass Graft (CABG): Prolonged Intubation: Percentage of	STS
164	patients aged 18 years and older undergoing isolated CABG surgery who require	
	postoperative intubation > 24 hours	
0130/	Coronary Artery Bypass Graft (CABG): Deep Sternal Wound Infection Rate:	STS
165	Percentage of patients aged 18 years and older undergoing isolated CABG surgery who,	
	within 30 days postoperatively, develop deep sternal wound infection involving muscle,	
	bone, and/or mediastinum requiring operative intervention	
0131/	Coronary Artery Bypass Graft (CABG): Stroke: Percentage of patients aged 18 years	STS
166	and older undergoing isolated CABG surgery who have a postoperative stroke (i.e., any	
	confirmed neurological deficit of abrupt onset caused by a disturbance in blood supply to	
	the brain) that did not resolve within 24 hours	

0114/	Coronary Artery Bypass Graft (CABG): Postoperative Renal Failure: Percentage of	STS
167	patients aged 18 years and older undergoing isolated CABG surgery (without pre-	
	existing renal failure) who develop postoperative renal failure or require dialysis	
0115/	Coronary Artery Bypass Graft (CABG): Surgical Re-Exploration: Percentage of	STS
168	patients aged 18 years and older undergoing isolated CABG surgery who require a return	
	to the operating room (OR) during the current hospitalization for mediastinal bleeding	
	with or without tamponade, graft occlusion, valve dysfunction, or other cardiac reason	
0116/	Coronary Artery Bypass Graft (CABG): Antiplatelet Medications at Discharge:	STS
169	Percentage of patients aged 18 years and older undergoing isolated CABG surgery who	
	were discharged on antiplatelet medication	
0117/	Coronary Artery Bypass Graft (CABG): Beta-Blockers Administered at Discharge:	STS
170	Percentage of patients aged 18 years and older undergoing isolated CABG surgery who	
	were discharged on beta-blockers	
0118/	Coronary Artery Bypass Graft (CABG): Anti-Lipid Treatment at Discharge:	STS
171	Percentage of patients aged 18 years and older undergoing isolated CABG surgery who	
	were discharged on a statin or other lipid-lowering regimen	

Finalized in the CY 2013 PFS final rule (see Table 100 at 77 FR 69274).

TABLE 59: Rheumatoid Arthritis (RA) Measures Group

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Finalized in the CY 2013 PFS final rule (see Table 101 at 77 FR 69274).

TABLE 60: Perioperative Care Measures Group

NQF/ PQRS	Measure Title and Description	Measure Developer
0270/	Perioperative Care: Timing of Prophylactic Parenteral Antibiotic – Ordering	AMA- PCPI/
20	Physician: Percentage of surgical patients aged 18 years and older undergoing	NCQA
	procedures with the indications for prophylactic parenteral antibiotics, who have an order	
	for prophylactic parenteral antibiotic to be given within one hour (if fluoroquinolone or	
	vancomycin, two hours), prior to the surgical incision (or start of procedure when no	
	incision is required)	
0268/	Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second	AMA- PCPI/
21	Generation Cephalosporin: Percentage of surgical patients aged 18 years and older	NCQA
	undergoing procedures with the indications for a first OR second generation	
	cephalosporin prophylactic antibiotic, who had an order for a first OR second generation	
	cephalosporin for antimicrobial prophylaxis	
0271/	Perioperative Care: Discontinuation of Prophylactic Parenteral Antibiotics (Non-	AMA- PCPI/
22	Cardiac Procedures): Percentage of non-cardiac surgical patients aged 18 years and	NCQA
	older undergoing procedures with the indications for prophylactic parenteral antibiotics	
	AND who received a prophylactic parenteral antibiotic, who have an order for	
	discontinuation of prophylactic parenteral antibiotics within 24 hours of surgical end	
	time	
0239/	Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When	AMA- PCPI/
23	Indicated in ALL Patients): Percentage of surgical patients aged 18 years and older	NCQA
	undergoing procedures for which VTE prophylaxis is indicated in all patients, who had	
	an order for Low Molecular Weight Heparin (LMWH), Low-Dose Unfractionated	
	Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be	
	given within 24 hours prior to incision time or within 24 hours after surgery end time	

Finalized in the CY 2013 PFS final rule (see Table 102 at 77 FR 69275).

TABLE 61: Back Pain Measures Group

NQF/ PQRS	Measure Title and Description	Measure Developer
0322/	Back Pain: Initial Visit: The percentage of patients aged 18 through 79 years with a	NCQA
148	diagnosis of back pain or undergoing back surgery who had back pain and function	
	assessed during the initial visit to the clinician for the episode of back pain	
0319/	Back Pain: Physical Exam: Percentage of patients aged 18 through 79 years with a	NCQA
149/	diagnosis of back pain or undergoing back surgery who received a physical examination	
	at the initial visit to the clinician for the episode of back pain	
0314/	Back Pain: Advice for Normal Activities: The percentage of patients aged 18 through	NCQA
150	79 years with a diagnosis of back pain or undergoing back surgery who received advice	
	for normal activities at the initial visit to the clinician for the episode of back pain	
0313/	Back Pain: Advice Against Bed Rest: The percentage of patients aged 18 through 79	NCQA
151	years with a diagnosis of back pain or undergoing back surgery who received advice	
	against bed rest lasting four days or longer at the initial visit to the clinician for the	
	episode of back pain	

Finalized in the CY 2013 PFS final rule (see Table 103 at 77 FR 69275).

TABLE 62: Hepatitis C Measures Group

NQF/ PQRS	Measure Title and Description	Measure Developer
0395/	Hepatitis C: Ribonucleic Acid (RNA) Testing Before Initiating Treatment:	AMA-PCPI
84	Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C	
	who started antiviral treatment within the 12 month reporting period for whom	
	quantitative hepatitis C virus (HCV) RNA testing was performed within 12 months prior	
	to initiation of antiviral treatment	
0396/	Hepatitis C: HCV Genotype Testing Prior to Treatment: Percentage of patients aged	AMA-PCPI
85	18 years and older with a diagnosis of chronic hepatitis C who started antiviral treatment	
	within the 12 month reporting period for whom hepatitis C virus (HCV) genotype testing	
	was performed within 12 months prior to initiation of antiviral treatment	
0398/	Hepatitis C: Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) Testing Between 4-	AMA-PCPI
87	12 Weeks After Initiation of Treatment: Percentage of patients aged 18 years and	
	older with a diagnosis of chronic hepatitis C who are receiving antiviral treatment for	
	whom quantitative hepatitis C virus (HCV) RNA testing was performed between 4-12	
	weeks after the initiation of antiviral treatment	
0399/	Hepatitis C: Hepatitis A Vaccination in Patients with Hepatitis C Virus (HCV):	AMA-PCPI
183	Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C	
	who have received at least one injection of hepatitis A vaccine, or who have documented	
	immunity to hepatitis A	

Finalized in the CY 2013 PFS final rule (see Table 104 at 77 FR 69275).

TABLE 63: Heart Failure (HF) Measures Group

NQF/ PQRS	Measure Title and Description	Measure Developer
0081/	Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or	AMA- PCPI/
5	Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic	ACCF/AHA
	Dysfunction (LVSD): Percentage of patients aged 18 years and older with a diagnosis of	
	heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40%	
	who were prescribed ACE inhibitor or ARB therapy either within a 12 month period	
	when seen in the outpatient setting OR at each hospital discharge	
0083/	Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic	AMA- PCPI/
8	Dysfunction (LVSD): Percentage of patients aged 18 years and older with a diagnosis of	ACCF/AHA
	heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40%	
	who were prescribed beta-blocker therapy either within a 12 month period when seen in	
	the outpatient setting OR at each hospital discharge	
0079/	Heart Failure: Left Ventricular Ejection Fraction (LVEF) Assessment: Percentage	AMA- PCPI/
198	of patients aged 18 years and older with a diagnosis of heart failure for whom the	ACCF/AHA
	quantitative or qualitative results of a recent or prior [any time in the past] LVEF	
	assessment is documented within a 12 month period	
0028/	Preventive Care and Screening: Tobacco Use: Screening and Cessation	AMA-PCPI
226	Intervention: Percentage of patients 18 years and older who were screened for tobacco	
	use one or more times within 24 months AND who received cessation counseling	
	intervention if identified as a tobacco user	

Finalized in the CY 2013 PFS final rule (see Table 105 at 77 FR 69276).

TABLE 64: Coronary Artery Disease (CAD) Measures Group

NQF/ PQRS	Measure Title and Description	Measure Developer
0067/	Coronary Artery Disease (CAD): Antiplatelet Therapy: Percentage of patients aged	AMA- PCPI/
6	18 years and older with a diagnosis of coronary artery disease seen within a 12 month	ACCF/AHA
	period who were prescribed aspirin or clopidogrel	
0074/	Coronary Artery Disease (CAD): Lipid Control: Percentage of patients aged 18 years	AMA- PCPI/
197	and older with a diagnosis of coronary artery disease seen within a 12 month period who	ACCF/AHA
	have a LDL-C result \leq 100 mg/dL OR patients who have a LDL-C result \geq 100 mg/dL	
	and have a documented plan of care to achieve LDL-C < 100 mg/dL, including at a	
	minimum the prescription of a statin	
0028/	Preventive Care and Screening: Tobacco Use: Screening and Cessation	AMA-PCPI
226	Intervention: Percentage of patients 18 years and older who were screened for tobacco	
	use one or more times within 24 months AND who received cessation counseling	
	intervention if identified as a tobacco user	
N/A/	Coronary Artery Disease (CAD): Symptom Management: Percentage of patients	AMA- PCPI/
242	aged 18 years and older with a diagnosis of coronary artery disease seen within a 12	ACCF/ AHA
	month period with results of an evaluation of level of activity and an assessment of	
	whether anginal symptoms are present or absent with appropriate management of anginal	
	symptoms within a 12 month period	

Finalized in the CY 2013 PFS final rule (see Table 106 at 77 FR 69276).

TABLE 65: Ischemic Vascular Disease (IVD) Measures Group

NQF/ PQRS	Measure Title and Description	Measure Developer
0068/	Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic:	NCQA
204	Percentage of patients 18 years of age and older who were discharged alive for acute	
	myocardial infarction (AMI), coronary artery bypass graft (CABG) or percutaneous	
	coronary interventions (PCI) in the 12 months prior to the measurement period, or who	
	had an active diagnosis of ischemic vascular disease (IVD) during the measurement	
	period and who had documentation of use of aspirin or another antithrombotic during the	
	measurement period	
0028/	Preventive Care and Screening: Tobacco Use: Screening and Cessation	AMA-PCPI
226	Intervention: Percentage of patients 18 years and older who were screened for tobacco	
	use one or more times within 24 months AND who received cessation counseling	
	intervention if identified as a tobacco user	
0018/	Controlling High Blood Pressure: Percentage of patients 18-85 years of age who had a	NCQA
236	diagnosis of hypertension and whose blood pressure was adequately controlled (< 140/90	
	mmHg) during the measurement period.	
0075/	Ischemic Vascular Disease (IVD): Complete Lipid Profile and LDL-C Control (<	NCQA
241	100 mg/dL): Percentage of patients 18 years of age and older who were discharged alive	
	for acute myocardial infarction (AMI), coronary artery bypass graft (CABG) or	
	percutaneous coronary interventions (PCI) in the 12 months prior to the measurement	
	period, or who had an active diagnosis of ischemic vascular disease (IVD) during the	
	measurement period, and who had each of the following during the measurement period:	
	a complete lipid profile and LDL-C was adequately controlled (< 100 mg/dL)	

Finalized in the CY 2013 PFS final rule (see Table 107 at 77 FR 69277).

TABLE 66: HIV/AIDS Measures Group

NQF/ PQRS	Measure Title and Description	Measure Developer
0404/	HIV/AIDS: CD4+ Cell Count or CD4+ Percentage Performed: Percentage of patients	NCQA
159	aged 6 months and older with a diagnosis of HIV/AIDS for whom a CD4+ cell count or	
	CD4+ cell percentage was performed at least once every 6 months	
0405/	HIV/AIDS: Pneumocystis Jiroveci Pneumonia (PCP) Prophylaxis: Percentage of	NCQA
160	patients aged 6 weeks and older with a diagnosis of HIV/AIDS who were prescribed	
	Pneumocystis Jiroveci Pneumonia (PCP) prophylaxis	
0409/	HIV/AIDS: Sexually Transmitted Disease Screening for Chlamydia, Gonorrhea,	AMA- PCPI/
205	and Syphilis: Percentage of patients aged 13 years and older with a diagnosis of	NCQA
	HIV/AIDS for whom chlamydia, gonorrhea and syphilis screenings were performed at	
2082/	least once since the diagnosis of HIV infection HIV Viral Load Suppression: The percentage of patients, regardless of age, with a	HRSA
		пкза
N/A	diagnosis of HIV with a HIV viral load less than 200 copies/mL at last HIV viral load	
	test during the measurement year	
2083/	Prescription of HIV Antiretroviral Therapy: Percentage of patients, regardless of age,	HRSA
N/A	with a diagnosis of HIV prescribed antiretroviral therapy for the treatment of HIV	
	infection during the measurement year	
2079/	HIV Medical Visit Frequency: Percentage of patients, regardless of age with a	HRSA
N/A	diagnosis of HIV who had at least one medical visit in each 6 month period of the 24	
	month measurement period, with a minimum of 60 days between medical visits	
2080/	Gap in HIV Medical Visits: Percentage of patients, regardless of age, with a diagnosis	HRSA
N/A	of HIV who did not have a medical visit in the last 6 months	

Finalized in the CY 2013 PFS final rule (see Table 108 at 77 FR 69277).

TABLE 67: Asthma Measures Group

NQF/ PQRS	Measure Title and Description	Measure Developer
0047/	Asthma: Pharmacologic Therapy for Persistent Asthma - Ambulatory Care Setting:	AMA- PCPI/
53	Percentage of patients aged 5 through 64 years with a diagnosis of persistent asthma who	NCQA
	were prescribed long-term control medication	
0001/	Asthma: Assessment of Asthma Control – Ambulatory Care Setting: Percentage of	AMA- PCPI/
64	patients aged 5 through 64 years with a diagnosis of asthma who were evaluated at least	NCQA
	once during the measurement period for asthma control (comprising asthma impairment	
	and asthma risk)	
N/A/	Asthma: Tobacco Use: Screening - Ambulatory Care Setting: Percentage of patients	AMA- PCPI/
231	aged 5 through 64 years with a diagnosis of asthma (or their primary caregiver) who	NCQA
	were queried about tobacco use and exposure to second hand smoke within their home	
	environment at least once during the one-year measurement period	
N/A/	Asthma: Tobacco Use: Intervention - Ambulatory Care Setting: Percentage of	AMA- PCPI/
232	patients aged 5 through 64 years with a diagnosis of asthma who were identified as	NCQA
	tobacco users (or their primary caregiver) who received tobacco cessation intervention at	
	least once during the one-year measurement period	

Finalized in the CY 2013 PFS final rule (see Table 109 at 77 FR 69277).

TABLE 68: Chronic Obstructive Pulmonary Disease (COPD) Measures Group

NQF/ PQRS	Measure Title and Description	Measure Developer
0091/	Chronic Obstructive Pulmonary Disease (COPD): Spirometry Evaluation:	AMA-PCPI
51	Percentage of patients aged 18 years and older with a diagnosis of COPD who had	
	spirometry evaluation results documented	
0102/	Chronic Obstructive Pulmonary Disease (COPD): Inhaled Bronchodilator	AMA-PCPI
52	Therapy: Percentage of patients aged 18 years and older with a diagnosis of COPD and	
	who have an FEV1/FVC less than 60% and have symptoms who were prescribed an	
	inhaled bronchodilator	
0041/	Preventive Care and Screening: Influenza Immunization: Percentage of patients aged	AMA-PCPI
110	6 months and older seen for a visit between October 1 and March 31 who received an	
	influenza immunization OR who reported previous receipt of an influenza immunization	
0043/	Pneumonia Vaccination Status for Older Adults: Percentage of patients 65 years of	NCQA
111	age and older who have ever received a pneumococcal vaccine	
0028/	Preventive Care and Screening: Tobacco Use: Screening and Cessation	AMA-PCPI
226	Intervention: Percentage of patients 18 years and older who were screened for tobacco	
	use one or more times within 24 months AND who received cessation counseling	
	intervention if identified as a tobacco user	

Finalized in the CY 2013 PFS final rule (see Table 110 at 77 FR 69278).

TABLE 69: Inflammatory Bowel Disease (IBD) Measures Group

NQF/ PQRS	Measure Title and Description	Measure Developer
0028/	Preventive Care and Screening: Tobacco Use: Screening and Cessation	AMA-PCPI
226	Intervention: Percentage of patients 18 years and older who were screened for tobacco	
	use one or more times within 24 months AND who received cessation counseling	
	intervention if identified as a tobacco user	
N/A/	Inflammatory Bowel Disease (IBD): Type, Anatomic Location and Activity All	AGA
269	Documented: Percentage of patients aged 18 years and older with a diagnosis of	
	inflammatory bowel disease who have documented the disease type, anatomic location	
	and activity, at least once during the reporting period	
N/A/	Inflammatory Bowel Disease (IBD): Preventive Care: Corticosteroid Sparing	AGA
270	Therapy: Percentage of patients aged 18 years and older with a diagnosis of	
	inflammatory bowel disease who have been managed by corticosteroids greater than or	
	equal to 10 mg/day for 60 or greater consecutive days that have been prescribed	
	corticosteroid sparing therapy in the last reporting year	
N/A/	Inflammatory Bowel Disease (IBD): Preventive Care: Corticosteroid Related	AGA
271	Iatrogenic Injury – Bone Loss Assessment: Percentage of patients aged 18 years and	
	older with a diagnosis of inflammatory bowel disease who have received dose of	
	corticosteroids greater than or equal to 10 mg/day for 60 or greater consecutive days and	
	were assessed for risk of bone loss once per the reporting year	

N/A/	Inflammatory Bowel Disease (IBD): Preventive Care: Influenza Immunization:	AGA
272	Percentage of patients aged 18 years and older with inflammatory bowel disease for	
	whom influenza immunization was recommended, administered or previously received	
	during the reporting year	
N/A/	Inflammatory Bowel Disease (IBD): Preventive Care: Pneumococcal Immunization:	AGA
273	Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel	
	disease that had pneumococcal vaccination administered or previously received	
N/A/	Inflammatory Bowel Disease (IBD): Testing for Latent Tuberculosis (TB) Before	AGA
274	Initiating Anti-TNF (Tumor Necrosis Factor) Therapy: Percentage of patients aged	
	18 years and older with a diagnosis of inflammatory bowel disease for whom a	
	tuberculosis (TB) screening was performed and results interpreted within 6 months prior	
	to receiving a first course of anti-TNF (tumor necrosis factor) therapy	
N/A/	Inflammatory Bowel Disease (IBD): Assessment of Hepatitis B Virus (HBV) Status	AGA
275	Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy: Percentage of patients	
	aged 18 years and older with a diagnosis of inflammatory bowel disease (IBD) who had	
	Hepatitis B Virus (HBV) status assessed and results interpreted within 1 year prior to	
	receiving a first course of anti-TNF (tumor necrosis factor) therapy	

Finalized in the CY 2013 PFS final rule (see Table 111 at 77 FR 69278).

TABLE 70: Sleep Apnea Measures Group

NQF/ PQRS	Measure Title and Description	Measure Developer
N/A/	Sleep Apnea: Assessment of Sleep Symptoms: Percentage of visits for patients aged 18	AMA- PCPI/
276	years and older with a diagnosis of obstructive sleep apnea that includes documentation	NCQA
	of an assessment of sleep symptoms, including presence or absence of snoring and	
	daytime sleepiness	
N/A/	Sleep Apnea: Severity Assessment at Initial Diagnosis: Percentage of patients aged 18	AMA- PCPI/
277	years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea	NCQA
	index (AHI) or a respiratory disturbance index (RDI) measured at the time of initial	
	diagnosis	
N/A/	Sleep Apnea: Positive Airway Pressure Therapy Prescribed: Percentage of patients	AMA- PCPI/
278	aged 18 years and older with a diagnosis of moderate or severe obstructive sleep apnea	NCQA
	who were prescribed positive airway pressure therapy	
N/A/	Sleep Apnea: Assessment of Adherence to Positive Airway Pressure Therapy:	AMA- PCPI/
279	Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive	NCQA
	sleep apnea who were prescribed positive airway pressure therapy who had	
	documentation that adherence to positive airway pressure therapy was objectively	
	measured	

Finalized in the CY 2013 PFS final rule (see Table 112 at 77 FR 69279).

TABLE 71: Dementia Measures Group

NQF/ PQRS	Measure Title and Description	Measure Developer
N/A /	Dementia: Staging of Dementia: Percentage of patients, regardless of age, with a	AMA-PCPI
280	diagnosis of dementia whose severity of dementia was classified as mild, moderate or	
	severe at least once within a 12 month period	

N/A /	Dementia: Cognitive Assessment: Percentage of patients, regardless of age, with a	AMA-PCPI
281	diagnosis of dementia for whom an assessment of cognition is performed and the results	
	reviewed at least once within a 12 month period	
N/A /	Dementia: Functional Status Assessment: Percentage of patients, regardless of age,	AMA-PCPI
282	with a diagnosis of dementia for whom an assessment of functional status is performed	
	and the results reviewed at least once within a 12 month period	
N/A /	Dementia: Neuropsychiatric Symptom Assessment: Percentage of patients, regardless	AMA-PCPI
283	of age, with a diagnosis of dementia and for whom an assessment of neuropsychiatric	
	symptoms is performed and results reviewed at least once in a 12 month period	
N/A /	Dementia: Management of Neuropsychiatric Symptoms: Percentage of patients,	AMA-PCPI
284	regardless of age, with a diagnosis of dementia who have one or more neuropsychiatric	
	symptoms who received or were recommended to receive an intervention for	
	neuropsychiatric symptoms within a 12 month period	
N/A /	Dementia: Screening for Depressive Symptoms: Percentage of patients, regardless of	AMA-PCPI
285	age, with a diagnosis of dementia who were screened for depressive symptoms within a	
	12 month period	
N/A /	Dementia: Counseling Regarding Safety Concerns: Percentage of patients, regardless	AMA-PCPI
286	of age, with a diagnosis of dementia or their caregiver(s) who were counseled or referred	
	for counseling regarding safety concerns within a 12 month period	
N/A /	Dementia: Counseling Regarding Risks of Driving: Percentage of patients, regardless	AMA-PCPI
287	of age, with a diagnosis of dementia or their caregiver(s) who were counseled regarding	
	the risks of driving and the alternatives to driving at least once within a 12 month period	
N/A /	Dementia: Caregiver Education and Support: Percentage of patients, regardless of	AMA-PCPI
288	age, with a diagnosis of dementia whose caregiver(s) were provided with education on	
	dementia disease management and health behavior changes AND referred to additional	
	sources for support within a 12 month period	
	d in the CV 2012 DEC final rule (see Table 112 et 77 ED (0270)	

Finalized in the CY 2013 PFS final rule (see Table 113 at 77 FR 69279).

TABLE 72: Parkinson's Disease Measures Group

NQF/ PQRS	Measure Title and Description	Measure Developer
N/A /	Parkinson's Disease: Annual Parkinson's Disease Diagnosis Review: All patients	AAN
289	with a diagnosis of Parkinson's disease who had an annual assessment including a	
	review of current medications (e.g., medications that can produce Parkinson-like signs or	
	symptoms) and a review for the presence of atypical features (e.g., falls at presentation	
	and early in the disease course, poor response to levodopa, symmetry at onset, rapid	
	progression [to Hoehn and Yahr stage 3 in 3 years], lack of tremor or dysautonomia) at	
	least annually	
N/A /	Parkinson's Disease: Psychiatric Disorders or Disturbances Assessment: All patients	AAN
290	with a diagnosis of Parkinson's disease who were assessed for psychiatric disorders or	
	disturbances (e.g., psychosis, depression, anxiety disorder, apathy, or impulse control	
	disorder) at least annually	
N/A /	Parkinson's Disease: Cognitive Impairment or Dysfunction Assessment: All patients	AAN
291	with a diagnosis of Parkinson's disease who were assessed for cognitive impairment or	
	dysfunction at least annually	

N/A /	Parkinson's Disease: Querying about Sleep Disturbances: All patients with a	AAN
292	diagnosis of Parkinson's disease (or caregivers, as appropriate) who were queried about	
	sleep disturbances at least annually	
N/A /	Parkinson's Disease: Rehabilitative Therapy Options: All patients with a diagnosis of	AAN
293	Parkinson's disease (or caregiver(s), as appropriate) who had rehabilitative therapy	
	options (e.g., physical, occupational, or speech therapy) discussed at least annually	
N/A /	Parkinson's Disease: Parkinson's Disease Medical and Surgical Treatment Options	AAN
294	Reviewed: All patients with a diagnosis of Parkinson's disease (or caregiver(s), as	
	appropriate) who had the Parkinson's disease treatment options (e.g., non-	
	pharmacological treatment, pharmacological treatment, or surgical treatment) reviewed	
	at least once annually	

Finalized in the CY 2013 PFS final rule (see Table 114 at 77 FR 69279).

TABLE 73: Hypertension Measures Group

NQF/ PQRS	Measure Title and Description	Measure Developer
0028/	Preventive Care and Screening: Tobacco Use: Screening and Cessation	AMA-PCPI
226	Intervention: Percentage of patients aged 18 years and older who were screened for	
	tobacco use one or more times within 24 months AND who received cessation	
	counseling intervention if identified as a tobacco user	
N/A/	Hypertension: Use of Aspirin or Other Antithrombotic Therapy: Percentage of	ABIM
295	patients aged 30 through 90 years old with a diagnosis of hypertension and are eligible	
	for aspirin or other antithrombotic therapy who were prescribed aspirin or other	
	antithrombotic therapy	
N/A/	Hypertension: Complete Lipid Profile: Percentage of patients aged 18 through 90	ABIM
296	years old with a diagnosis of hypertension who received a complete lipid profile within	
	<u>60 months</u>	
N/A/	Hypertension: Urine Protein Test: Percentage of patients aged 18 through 90 years old	ABIM
297	with a diagnosis of hypertension who either have chronic kidney disease diagnosis	
	documented or had a urine protein test done within 36 months	
N/A/	Hypertension: Annual Serum Creatinine Test: Percentage of patients aged 18 through	ABIM
298	90 years old with a diagnosis of hypertension who had a serum creatinine test done	
	within 12 months	
N/A/	Hypertension: Diabetes Mellitus Screening Test: Percentage of patients aged 18	ABIM
299	through 90 years old with a diagnosis of hypertension who had a diabetes screening test	
	within <u>36 months</u>	
N/A/	Hypertension: Blood Pressure Control: Percentage of patients aged 18 through 90	ABIM
300	years old with a diagnosis of hypertension whose most recent blood pressure was under	
	control (< 140/90 mmHg)	
N/A/	Hypertension: Low Density Lipoprotein (LDL-C) Control: Percentage of patients	ABIM
301	aged 18 through 90 years old with a diagnosis of hypertension whose most recent LDL	
	cholesterol level was under control (at goal)	
N/A/	Hypertension: Dietary and Physical Activity Modifications Appropriately	ABIM
302	Prescribed: Percentage of patients aged 18 through 90 years old with a diagnosis of	
	hypertension who received dietary and physical activity counseling at least once within	
	12 months	

Finalized in the CY 2013 PFS final rule (see Table 115 at 77 FR 69280).

TABLE 74: Cardiovascular Prevention Measures Group

NQF/ PQRS	Measure Title and Description	Measure Developer
0064/	Diabetes: Low Density Lipoprotein (LDL-C) Control (< 100 mg/dL): Percentage of	NCQA
2	patients 18-75 years of age with diabetes whose LDL-C was adequately controlled	
	(<100 mg/dL) during the measurement	
0068/	Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic:	NCQA
204	Percentage of patients 18 years of age and older who were discharged alive for acute	
	myocardial infarction (AMI), coronary artery bypass graft (CABG) or percutaneous	
	coronary interventions (PCI) in the 12 months prior to the measurement period, or who	
	had an active diagnosis of ischemic vascular disease (IVD) during the measurement	
	period and who had documentation of use of aspirin or another antithrombotic during the	
	measurement period	
0028/	Preventive Care and Screening: Tobacco Use: Screening and Cessation	AMA-PCPI
226	Intervention: Percentage of patients 18 years and older who were screened for tobacco	
	use one or more times within 24 months AND who received cessation counseling	
	intervention if identified as a tobacco user	
0018/	Controlling High Blood Pressure: Percentage of patients 18-85 years of age who had a	NCQA
236	diagnosis of hypertension and whose blood pressure was adequately controlled (< 140/90	
	mmHg) during the measurement period.	
0075/	Ischemic Vascular Disease (IVD): Complete Lipid Profile and LDL-C Control (<	NCQA
241	100 mg/dL): Percentage of patients 18 years of age and older who were discharged alive	
	for acute myocardial infarction (AMI), coronary artery bypass graft (CABG) or	
	percutaneous coronary interventions (PCI) in the 12 months prior to the measurement	
	period, or who had an active diagnosis of ischemic vascular disease (IVD) during the	
	measurement period, and who had each of the following during the measurement period:	
	a complete lipid profile and LDL-C was adequately controlled (< 100 mg/dL)	
N/A/	Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up	CMS
317	Documented: Percentage of patients aged 18 years and older seen during the reporting	
	period who were screened for high blood pressure (BP) AND a recommended follow-up	
	plan is documented based on the current blood pressure reading as indicated	

Finalized in the CY 2013 PFS final rule (see Table 116 at 77 FR 69280).

TABLE 75: Cataracts Measures Group

NQF/ PQRS	Measure Title and Description	Measure Developer
0565/	Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract	AMA- PCPI/
191	Surgery: Percentage of patients aged 18 years and older with a diagnosis of uncomplicated cataract who had cataract surgery and no significant ocular conditions impacting the visual outcome of surgery and had best-corrected visual acuity of 20/40 or better (distance or near) achieved within 90 days following the cataract surgery	NCQA

0564/	Cataracts: Complications within 30 Days Following Cataract Surgery Requiring	AMA- PCPI/
192	Additional Surgical Procedures: Percentage of patients aged 18 years and older with a	NCQA
	diagnosis of uncomplicated cataract who had cataract surgery and had any of a specified	
	list of surgical procedures in the 30 days following cataract surgery which would indicate	
	the occurrence of any of the following major complications: retained nuclear fragments,	
	endophthalmitis, dislocated or wrong power IOL, retinal detachment, or wound	
	dehiscence	
N/A/	Cataracts: Improvement in Patient's Visual Function within 90 Days Following	AAO
303	Cataract Surgery: Percentage of patients aged 18 years and older in sample who had	
	cataract surgery and had improvement in visual function achieved within 90 days	
	following the cataract surgery, based on completing a pre-operative and post-operative	
	visual function survey	
N/A/	Cataracts: Patient Satisfaction within 90 Days Following Cataract Surgery:	AAO
304	Percentage of patients aged 18 years and older in sample who had cataract surgery and	
	were satisfied with their care within 90 days following the cataract surgery, based on	
	completion of the Consumer Assessment of Healthcare Providers and Systems Surgical	
	Care Survey	

Finalized in the CY 2013 PFS final rule (see Table 117 at 77 FR 69281).

TABLE 76: Oncology Measures Group

NQF/	Measure Title and Description	Measure
PQRS	Post of Control House LTL and Control HICE Annual	Developer
0387/	Breast Cancer: Hormonal Therapy for Stage IC -IIIC Estrogen	AMA-PCPI/
71	Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer: Percentage of	ASCO/NCCN
	female patients aged 18 years and older with Stage IC through IIIC, ER or PR positive	
	breast cancer who were prescribed tamoxifen or aromatase inhibitor (AI) during the 12-month reporting period	
0385/	Colon Cancer: Chemotherapy for AJCC Stage III Colon Cancer Patients:	AMA-PCPI/
72	Percentage of patients aged 18 through 80 years with AJCC Stage III colon cancer who	ASCO/NCCN
	are referred for adjuvant chemotherapy, prescribed adjuvant chemotherapy, or have	
	previously received adjuvant chemotherapy within the 12-month reporting period	
0041/	Preventive Care and Screening: Influenza Immunization: Percentage of patients aged	AMA-PCPI
110	6 months and older seen for a visit between October 1 and March 31 who received an	
	influenza immunization OR who reported previous receipt of an influenza immunization	
0419/	Documentation of Current Medications in the Medical Record: Percentage of visits	CMS
130	for patients aged 18 years and older for which the eligible professional attests to	
	documenting a list of current medications using all immediate resources available on the	
	date of the encounter. This list <u>must</u> include ALL known prescriptions, over-the-	
	counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND <u>must</u>	
	contain the medications' name, dosage, frequency and route of administration.	
0384/	Oncology: Medical and Radiation – Pain Intensity Quantified: Percentage of	AMA-PCPI
143	patients, regardless of patient age, with a diagnosis of cancer currently receiving	
	chemotherapy or radiation therapy in which pain intensity is quantified	
0383/	Oncology: Medical and Radiation – Plan of Care for Pain: Percentage of visits for	AMA-PCPI
144	patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy	
	or radiation therapy who report having pain with a documented plan of care to address	
	pain	

0386/	Oncology: Cancer Stage Documented: Percentage of patients, regardless of age, with a	AMA- PCPI/
194	diagnosis of cancer who are seen in the ambulatory setting who have a baseline	ASCO
	American Joint Committee on Cancer (AJCC) cancer stage or documentation that the	
	cancer is metastatic in the medical record at least once during the 12 month reporting	
	period	
0028/	Preventive Care and Screening: Tobacco Use: Screening and Cessation	AMA-PCPI
226	Intervention: Percentage of patients 18 years and older who were screened for tobacco	
	use one or more times within 24 months AND who received cessation counseling	
	intervention if identified as a tobacco user	

Finalized in the CY 2013 PFS final rule (see Table 118 at 77 FR 69281).

TABLE 77: Total Knee Replacement Measures Group

NQF/ PQRS	Measure Title	Measure Developer
N/A / N/A	Total Knee Replacement: Shared Decision-Making: Trial of Conservative (Non-surgical) Therapy: Percentage of patients regardless of age or gender undergoing a total knee replacement with documented shared decision-making with discussion of conservative (non-surgical) therapy prior to the procedure	AAHKS
N/A / N/A	Total Knee Replacement: Venous Thromboembolic and Cardiovascular Risk Evaluation: Percentage of patients regardless of age or gender undergoing a total knee replacement who are evaluated for the presence or absence of venous thromboembolic and cardiovascular risk factors within 30 days prior to the procedure including history of Deep Vein Thrombosis, Pulmonary Embolism, Myocardial Infarction, Arrhythmia and Stroke	AAHKS
N/A / N/A	Total Knee Replacement: Preoperative Antibiotic Infusion with Proximal Tourniquet: Percentage of patients regardless of age undergoing a total knee replacement who had the prophylactic antibiotic completely infused prior to the inflation of the proximal tourniquet	AAHKS
N/A / N/A	Total Knee Replacement: Identification of Implanted Prosthesis in Operative Report: Percentage of patients regardless of age or gender undergoing total knee replacement whose operative report identifies the prosthetic implant specifications including the prosthetic implant manufacturer, the brand name of the prosthetic implant and the size of prosthetic implant	AAHKS

Finalized in the CY 2013 PFS final rule (see Table 120 at 77 FR 69283).

TABLE 78: General Surgery Measures Group

NQF/ PQRS	Measure Title	Measure Developer
N/A/	Anastomotic Leak Intervention: Percentage of patients aged 18 years and	ACS
N/A	older who required an anastomotic leak intervention following gastric bypass or	
	colectomy surgery	
N/A/	Unplanned Reoperation within the 30 Day Postoperative Period: Percentage	ACS
N/A	of patients aged 18 years and older who had any unplanned reoperation within	
	the 30 day postoperative period	

N/A/	Unplanned Hospital Readmission within 30 Days of Principal Procedure:	ACS
N/A	Percentage of patients aged 18 years and older who had an unplanned hospital	
	readmission within 30 days of principal procedure	
N/A/	Surgical Site Infection (SSI): Percentage of patients aged 18 years and older	ACS
N/A	who had a surgical site infection (SSI)	
N/A/	Patient-Centered Surgical Risk Assessment and Communication: Percentage	ACS
N/A	of patients who underwent a non-emergency surgery who had their personalized	
	risks of postoperative complications assessed by their surgical team prior to	
	surgery using a clinical data-based, patient-specific risk calculator and who	
	received personal discussion of those risks with the surgeon	

TABLE 79: Optimizing Patient Exposure to Ionizing Radiation Measures Group

NQF/ PQRS	Measure Title	
N/A/	Optimizing Patient Exposure to Ionizing Radiation: Utilization of a Standardized	AMA-PCPI
N/A	Nomenclature for Computed Tomography (CT) Imaging Description: Percentage of	
	computed tomography (CT) imaging reports for all patients, regardless of age, with the	
	imaging study named according to a standardized nomenclature and the standardized	
	nomenclature is used in institution's computer systems	
N/A/	Optimizing Patient Exposure to Ionizing Radiation: Count of Potential High Dose	AMA-PCPI
N/A	Radiation Imaging Studies: Computed Tomography (CT) and Cardiac Nuclear	
	Medicine Studies: Percentage of computed tomography (CT) and cardiac nuclear	
	medicine (myocardial perfusion studies) imaging reports for all patients, regardless of	
	age, that document a count of known previous CT (any type of CT) and cardiac nuclear	
	medicine (myocardial perfusion) studies that the patient has received in the 12-month	
	period prior to the current study	
N/A/	Optimizing Patient Exposure to Ionizing Radiation: Reporting to a Radiation Dose	AMA-PCPI
N/A	Index Registry: Percentage of total computed tomography (CT) studies performed for	
	all patients, regardless of age, that are reported to a radiation dose index registry AND	
	that include at a minimum selected data elements	
N/A/	Optimizing Patient Exposure to Ionizing Radiation: Computed Tomography (CT)	AMA-PCPI
N/A	Images Available for Patient Follow-up and Comparison Purposes: Percentage of	
	final reports for computed tomography (CT) studies performed for all patients, regardless	
	of age, which document that Digital Imaging and Communications in Medicine	
	(DICOM) format image data are available to non-affiliated external entities on a secure,	
	media free, reciprocally searchable basis with patient authorization for at least a 12-	
	month period after the study	
N/A/	Optimizing Patient Exposure to Ionizing Radiation: Search for Prior Computed	AMA-PCPI
N/A	Tomography (CT) Imaging Studies Through a Secure, Authorized, Media-Free,	
	Shared Archive: Percentage of final reports of computed tomography (CT) studies	
	performed for all patients, regardless of age, which document that a search for Digital	
	Imaging and Communications in Medicine (DICOM) format images was conducted for	
	prior patient CT imaging studies completed at non-affiliated external entities within the	
	past 12-months and are available through a secure, authorized, media free, shared archive	
	prior to an imaging study being performed	

N/A/	Optimizing Patient Exposure to Ionizing Radiation: Appropriateness: Follow-up	AMA-PCPI			
N/A	CT Imaging for Incidentally Detected Pulmonary Nodules According to				
	Recommended Guidelines: Percentage of final reports for CT imaging studies of the				
	thorax for patients aged 18 years and older with documented follow-up recommendations				
	for incidentally detected pulmonary nodules (eg, follow-up CT imaging studies needed				
	or that no follow-up is needed) based at a minimum on nodule size AND patient risk				
	factors				

c. Final Measures Available for Reporting in the GPRO Web Interface

For ease of reference, Table 80 specifies the measures that are available for reporting in the GPRO web interface for 2014 and beyond. Please note that this is a total list of the measures that will be reported by a group practice using the GPRO web interface in 2014, and all measures contained within this table were previously finalized in the CY 2013 PFS final rule (77 FR 69269).

TABLE 80: Measures in the Group Practice Reporting Option Web Interface for 2014 and Beyond

NQF/ PQRS	GPRO Disease Module	NQS Domain	Measure and Title Description ¹	Measure Steward	Other Quality Reporting Programs
0059/	Diabetes	Effective Clinical Care	Diabetes: Hemoglobin A1c	NCQA	MU2
1	Mellitus		Poor Control: Percentage of		ACO
			patients 18-75 years of age with		
			diabetes who had hemoglobin		
			A1c > 9.0% during the		
			measurement period		
0083/	Heart Failure	Effective Clinical Care	Heart Failure (HF): Beta-	AMA- PCPI/	MU2
8			Blocker Therapy for Left	ACCF/	ACO
			Ventricular Systolic	AHA	
			Dysfunction (LVSD):		
			Percentage of patients aged 18		
			years and older with a diagnosis		
			of heart failure (HF) with a		
			current or prior left ventricular		
			ejection fraction (LVEF) < 40%		
			who were prescribed beta-		
			blocker therapy either within a		
			12 month period when seen in		
			the outpatient setting OR at		
			each hospital discharge		

NQF/ PQRS	GPRO Disease Module	NQS Domain	Measure and Title Description [*]	Measure Steward	Other Quality Reporting Programs
0097/46	Care Coordination/ Patient Safety	Patient Safety	Medication Reconciliation: Percentage of patients aged 65 years and older discharged from any inpatient facility (e.g. hospital, skilled nursing facility, or rehabilitation facility) and seen within 30 days following discharge in the office by the physician, prescribing practitioner, registered nurse, or clinical pharmacist providing on-going care who had a reconciliation of the discharge medications with the current medication list in the outpatient medical record documented	AMA- PCPI/ NCQA	ACO
0041/	Preventive Care	Community/Population Health	Preventive Care and Screening: Influenza Immunization: Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization	AMA-PCPI	MU2 ACO
0043/	Preventive Care	Effective Clinical Care	Pneumonia Vaccination Status for Older Adults: Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine	NCQA	MU2 ACO
N/A/ 112	Preventive Care	Effective Clinical Care	Breast Cancer Screening: Percentage of women 50 through 74 years of age who had a mammogram to screen for breast cancer within 27 months	NCQA	MU2 ACO
0034/	Preventive Care	Effective Clinical Care	Colorectal Cancer Screening: Percentage of patients 50 through 75 years of age who had appropriate screening for colorectal cancer	NCQA	MU2 ACO

NQF/ PQRS	GPRO Disease Module	NQS Domain	Measure and Title Description [†]	Measure Steward	Other Quality Reporting	Programs
0066/	Coronary Artery Disease	Effective Clinical Care	Coronary Artery Disease (CAD): Angiotensin- Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%): Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who also have diabetes OR a current or prior Left Ventricular Ejection Fraction (LVEF) < 40% who were prescribed ACE	AMA-PCPI/ACCF/AHA	ACO	
0421/128	Preventive Care	Community/Population Health	Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow- Up: Percentage of patients aged 18 years and older with a documented BMI during the current encounter or during the previous 6 months AND when the BMI is outside of normal parameters, a follow-up plan is documented during the encounter or during the previous 6 months of the encounter Normal Parameters: Age 65 years and older BMI ≥ 23 and < 30; Age 18-64 years BMI ≥ 18.5 and < 25	CMS	MU2 ACO	

NQF/ PQRS	GPRO Disease Module	NQS Domain	Measure and Title Description ³	Measure	Other Quality Reporting Programs
0418/	Preventive	Community/Population	Preventive Care and	CMS	MU2
134	Care	Health	Screening: Screening for		ACO
			Clinical Depression and		
			Follow-Up Plan: Percentage of		
			patients aged 12 years and older		
			screened for clinical depression		
			on the date of the encounter		
			using an age appropriate		
			standardized depression		
			screening tool AND if positive,		
			a follow-up plan is documented		
00=4/			on the date of the positive screen	And Dept	
0074/	Coronary	Effective Clinical Care	Coronary Artery Disease	AMA- PCPI/	ACO
197	Artery		(CAD): Lipid Control:	ACCF/	
	Disease		Percentage of patients aged 18	AHA	
			years and older with a diagnosis of coronary artery disease seen		
			within a 12 month period who		
			have a LDL-C result < 100		
			mg/dL OR patients who have a		
			LDL-C result $\geq 100 \text{ mg/dL}$ and		
			have a documented plan of care		
			to achieve LDL-C < 100mg/dL,		
			including at a minimum the		
			prescription of a statin		

NQF/ PQRS	GPRO Disease Module	NQS Domain	Measure and Title Description [‡]	Measure Steward	Other Quality Reporting Programs
0068/	Ischemic Vascular Disease	Effective Clinical Care	Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic: Percentage of patients 18 years of age and older who were	NCQA	MU2 ACO Million Hearts
			discharged alive for acute myocardial infarction (AMI), coronary artery bypass graft (CABG) or percutaneous coronary interventions (PCI) in		
			the 12 months prior to the measurement period, or who had an active diagnosis of ischemic vascular disease (IVD) during the measurement period and		
			who had documentation of use of aspirin or another antithrombotic during the measurement period		
0028/226	Preventive Care	Community/Population Health	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months <u>AND</u> who received cessation counseling intervention if identified as a tobacco user	AMA-PCPI	MU2 ACO Million Hearts
0018/236	Hypertension	Effective Clinical Care	Controlling High Blood Pressure: Percentage of patients 18-85 years of age who had a diagnosis of hypertension and whose blood pressure was adequately controlled (< 140/90 mmHg) during the measurement period.	NCQA	MU2 ACO Million Hearts

NQF/ PQRS	GPRO Disease Module	NQS Domain	Measure and Title Description	Measure Steward	Other Quality Reporting Programs
0075/241	Ischemic Vascular Disease	Effective Clinical Care	Ischemic Vascular Disease (IVD): Complete Lipid Profile and (LDL-C) Control (<100 mg/dL): Percentage of patients 18 years of age and older who were discharged alive for acute myocardial infarction (AMI), coronary artery bypass graft (CABG) or percutaneous coronary interventions (PCI) in the 12 months prior to the measurement period, or who had an active diagnosis of ischemic vascular disease (IVD) during the measurement period, and who had each of the following during the measurement period: a complete lipid profile and LDL-C was adequately	NCQA	MU2 ACO Million Hearts
N/A/ 317	Preventive Care	Community/Population Health	controlled (< 100 mg/dL) Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented: Percentage of patients aged 18 years and older seen during the measurement period who were screened for high blood pressure (BP) AND a recommended follow-up plan is documented based on the current blood pressure reading as indicated	CMS	MU2 ACO Million Hearts
0101/318	Care Coordination/ Patient Safety	Patient Safety	Falls: Screening for Fall Risk: Percentage of patients 65 years of age and older who were screened for future fall risk at least once during the measurement period	NCQA	MU2 ACO

GPRO Disease Module	NQS Domain	Measure and Title Description ¹	Measure Steward	Other Quality Reporting Programs
Diabetes	Effective Clinical Care	Diabetes Composite: Optimal	MNCM	ACO
Mellitus		Diabetes Care: Patients ages 18		
		through 75 with a diagnosis of		
		diabetes, who meet all the		
		numerator targets of this		
		composite measure:		
		• $A1c < 8.0\%$		
		• LDL < 100 mg/dL		
		blood pressure <		
		140/90 mmHg		
	Disease Module	Disease Module NQS Domain Diabetes Effective Clinical Care	Disease Module Measure and Title Description*	Diabetes Mellitus Effective Clinical Care Diabetes Composite: Optimal Diabetes Care: Patients ages 18 through 75 with a diagnosis of diabetes, who meet all the numerator targets of this composite measure: • A1c < 8.0% • LDL < 100 mg/dL • blood pressure < 140/90 mmHg • tobacco non-user and • (for patients with a diagnosis of ischemic vascular disease) daily aspirin use unless

[¥] Titles and descriptions in this table are aligned with the 2014 Physician Quality Reporting System Claims and Registry measure titles and descriptions, and may differ from existing measures in other programs. Please reference the National Quality Forum (NQF) and Physician Quality Reporting System numbers for clarification.

d. The Clinician Group (CG) Consumer Assessment of Healthcare Providers and Systems (CAHPS) Survey

Because we believed these patient surveys are important tools for assessing beneficiary experience of care and outcomes, under our authority under section 1848(m)(3)(C) of the Act to select the measures for which a group practice must report, we proposed a new satisfactory reporting criterion in this the proposed rule to provide group practices comprised of 25 or more eligible professionals the option to complete the CG CAHPS survey for purposes of satisfying the 2014 PQRS incentive and 2016 PQRS payment adjustment (78 FR 43476). Specifically, we proposed the following 12 summary the survey measures to use for the PQRS program:

- Getting timely care, appointments, and information.
- How well providers Communicate.
- Patient's Rating of Provider.
- Access to Specialists.

- Health Promotion & Education.
- Shared Decision Making.
- Health Status/Functional Status.
- Courteous and Helpful Office Staff.
- Care Coordination.
- Between Visit Communication.
- Helping Your to Take Medication as Directed.
- Stewardship of Patient Resources.

The first seven measures proposed above are the same ones used in the Medicare Shared Savings Programs. We believe it is important to align measures across programs to the extent possible. The remaining five measures proposed above address areas of high importance to Medicare and are areas where patient experience can inform the quality of care related to care coordination and efficiency. We noted that under this proposal, the group practice would bear the cost of having this survey administered. We solicited and received the following public comments on these proposed measures:

Comment: Several commenters generally supported the addition of a GPRO option to report the CG CAHPS survey measures for the 2014 PQRS incentive. However, some commenters have concerns that, since the survey's questions focus on primary care issues, the surveys are not widely applicable to services provided by certain specialists. Some of these commenters requested that, in addition to allowing reporting of the CG CAHPS survey measures, surgical group practices in the GPRO also be allowed to report on the Consumer Assessment of Healthcare Providers Surgical Care Survey (S-CAHPS) as these survey measures are more relevant to their practice.

Response: We appreciate the commenters' positive feedback and are therefore finalizing this proposed criterion, as proposed. For the commenters' request to allow surgical group practices to report on S-CAHPS survey measures, we generally agree that the S-CAHPS survey measures would be more relevant to a surgical group practice than the CG CAHPS measures. Unfortunately, at this time, we cannot introduce the S-CAHPS measures for reporting in the PQRS GPRO for 2014, since the Measure

Applications Partnership (MAP) has not yet had an opportunity to review the S-CAHPS survey measures. Please note that section 1890A of the Act, which was added by section 3014(b) of the Affordable Care Act, requires that the entity with a contract with the Secretary under section 1890(a) of the Act (currently that, is the NQF) convene multi-stakeholder groups, currently the MAP, to provide input to the Secretary on the selection of certain categories of quality and efficiency measures. As such, prior to inclusion in the PQRS measure set, the S-CAHPS survey measures must be submitted to the MAP for review.

<u>Comment</u>: One commenter expressed concern with "survey fatigue." This commenter is concerned that some patients will receive multiple surveys asking very similar questions, which will likely to result in low response rates.

Response: We appreciate the comment and concern raised regarding "survey fatigue." CMS recognizes that there are multiple CAHPS survey efforts and takes steps to ensure that we are not duplicating patients in survey samples, as well as varies the timing in which it disseminates the survey.

Based on the comments received and for the reasons stated previously, we are finalizing the CG CAHPS measures, as proposed. A full description of the CG CAHPS survey measures is available at http://acocahps.cms.gov/Content/Default.aspx#aboutSurvey.

11. Statutory Requirements and Other Considerations for the Selection of PQRS Quality Measures for Meeting the Criteria for Satisfactory Participation in a Qualified Clinical Data Registry for 2014 and Beyond for Individual Eligible Professionals

For the measures for which eligible professionals participating in a qualified clinical data registry must report, section 1848(m)(3)(D) of the Act, as amended and added by section 601(b) of the American Tax Relief Act of 2012, provides that the Secretary shall treat eligible professionals as satisfactorily submitting data on quality measures if they satisfactorily participate in a qualified clinical data registry. Section 1848(m)(3)(E) of the Act, as added by section 601(b) of the ATRA, provides some flexibility with regard to the types of measures applicable to satisfactory participation in a qualified clinical data registry, by specifying that for measures used by a qualified clinical data registry, sections 1890(b)(7) and

1890A(a) of the Act shall not apply, and measures endorsed by the entity with a contract with the Secretary under section 1890(a) of the Act may be used.

We proposed to provide to qualified clinical data registries flexibility with regard to choosing the quality measures data available for individual eligible professionals to choose from to report to CMS using these qualified clinical data registries (78 FR 43476). We believe it is preferable for the qualified clinical data registries with flexibility in selecting measures since we believe these clinical data registries would know best what measures should be reported to achieve the goal of improving the quality of care furnished by their eligible professionals. Although we proposed to allow these clinical data registries to determine the quality measures from which individual eligible professionals would choose to have reported to CMS, to ensure that CMS receives the same type of data that could be uniformly analyzed by CMS and sufficient measure data, we believe it is important to set parameters on the measures to be reported on and the types of measures should be reported to CMS. Therefore, we proposed requirements for the measures that would have to be reported to CMS by a qualified clinical data registry for the purpose of its individual eligible professionals meeting the criteria for satisfactory participation under the PQRS (78 FR 43476-43477). Below we have listed those proposed requirements and provided a summary of the comments received and our responses directly following each proposed requirement. We also received the following general comments on these proposals:

<u>Comment</u>: Several commenters generally supported our proposal to allow qualified clinical data registries to choose which measures will be reported to the PQRS on behalf of its participating eligible professional, as this provides flexibility in this reporting option. However, one commenter opposed allowing qualified clinical data registries to choose which measures its participants will report for purposes of the PQRS, because the measures reported by a qualified clinical data registry on behalf of an eligible professional may not be as robust as the measures finalized in the PQRS measure set.

Response: We appreciate the commenters' positive feedback and agree that it provides flexibility. For the opposing comment, we understand the commenter's concerns and expect that the measures reported by qualified clinical data registries are as robust and meaningful as those finalized in the PQRS

measure set. We are finalizing requirements – such as the requirements related to bench marking and the risk adjustment of certain measures – for the qualified clinical data registries that ensure that entities selected to become qualified clinical data registries have measures that are as robust as the measures contained in the PQRS measure set. Therefore, we believe our desire to provide flexibility in the measures that may be reported by a qualified clinical data registry outweighs our concern that the measures reported by a qualified clinical data registry may not be as robust as the measures finalized in the PQRS measure set.

We invited and received the following public comments on the proposed requirements for the measures the qualified clinical data registry would report to CMS for the individual eligible professional:

- The qualified clinical data registry must have at least 9 measures, covering at least 3 of the 6 NQS domains, available for reporting. The 6 NQS domains are as follows:
- ++ Person and Caregiver-Centered Experience and Outcomes. These are measures that reflect the potential to improve patient-centered care and the quality of care delivered to patients. They emphasize the importance of collecting patient-reported data and the ability to impact care at the individual patient level, as well as the population level through greater involvement of patients and families in decision making, self-care, activation, and understanding of their health condition and its effective management.
- ++ <u>Patient Safety</u>. These are measures that reflect the safe delivery of clinical services in both hospital and ambulatory settings and include processes that would reduce harm to patients and reduce burden of illness. These measures should enable longitudinal assessment of condition-specific, patient-focused episodes of care.
- ++ Communication and Care Coordination. These are measures that demonstrate appropriate and timely sharing of information and coordination of clinical and preventive services among health professionals in the care team and with patients, caregivers, and families to improve appropriate and timely patient and care team communication.

++ Community/Population Health. These are measures that reflect the use of clinical and preventive services and achieve improvements in the health of the population served. These are outcome-focused and have the ability to achieve longitudinal measurement that will demonstrate improvement or lack of improvement in the health of the US population.

- ++ Efficiency and Cost Reduction. These are measures that reflect efforts to significantly improve outcomes and reduce errors. These measures also impact and benefit a large number of patients and emphasize the use of evidence to best manage high priority conditions and determine appropriate use of healthcare resources.
- ++ <u>Effective Clinical Care</u>. These are measures that reflect clinical care processes closely linked to outcomes based on evidence and practice guidelines.

We solicited and received the following public comment on this proposal:

<u>Comment</u>: Some commenters supported our proposal to require that measures are reported according to their NQS domains. However, some commenters suggested that we use domains created by AHRQ rather than the NQS domains.

Response: We appreciate the commenters' support. For the commenters who suggested that we use domains created by AHRQ, in an effort to align how these measures are analyzed, we prefer to use the NQS domains. Based on the comments received and since we are finalizing satisfactory participation criterion relating to the reporting of 9 measures covering at least 3 NQS domains, we are finalizing the requirement that a qualified clinical data registry must have at least 9 measures, covering at least 3 of the 6 NQS domains, available for reporting, as proposed.

• The qualified clinical data registry must have at least 1 outcome measure available for reporting, which is a measure that assesses the results of health care that are experienced by patients (that is, patients' clinical events; patients' recovery and health status; patients' experiences in the health system; and efficiency/cost). We solicited and received the following public comment on this proposal:

<u>Comment</u>: Some commenters generally supported this proposal. Some commenters requested further clarification regarding the definition of an outcome measure.

Response: An outcome measure, as defined within the CMS Measures Management System Blueprint v10.0, indicates the result of the performance (or nonperformance) of functions or processes. It is a measure that focuses on achieving a particular state of health. PY 2014 examples of outcome measures within the PQRS include Measure #1: Diabetes: Hemoglobin A1c Poor Control, Measure #258: Rate of Open Repair of Small or Moderate Non-Ruptured Abdominal Aortic Aneurysms (AAA) without Major Complications (Discharged to Home by Post-Operative Day #7), or Measure #303: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery.

Please note that, even though the one of the criterion for satisfactory participation in a qualified clinical data registry does not require the reporting of at least 1 outcome measure, we are still finalizing this requirement, as proposed.

• The qualified clinical data registry may report on process measures, which are measures that focus on a process which leads to a certain outcome, meaning that a scientific basis exists for believing that the process, when executed well, will increase the probability of achieving a desired outcome. We solicited and received the following public comment on this proposal:

Comment: Some commenters generally supported this proposal.

<u>Response</u>: We appreciate the commenters' support for this proposal. For the reasons stated above and based on the comments received, we are finalizing this requirement, as proposed.

• The outcome and process measures reported must contain denominator data. That is, the lower portion of a fraction used to calculate a rate, proportion, or ratio. The denominator must describe the population eligible (or episodes of care) to be evaluated by the measure. This should indicate age, condition, setting, and timeframe (when applicable). For example, "Patients aged 18 through 75 years with a diagnosis of diabetes." We solicited and received the following public comment on this proposal:

<u>Comment</u>: Some commenters generally supported this proposal. Other commenters suggested that this requirement was overly restrictive. The commenters believed that qualified clinical data registries should be free to report on measures that do not conform to the way a PQRS measure is structured (such as requiring that measures contain denominator data).

Response: We appreciate the commenters' support for this proposal. For commenters who believe that the qualified clinical data registries should be free to report on measures that do not conform to the PQRS measure structure, particularly containing denominator data, we agree that there are measures that are not structured like PQRS measures that achieve the same goal as PQRS-structured measures of monitoring processes and outcomes. However, for CMS to be able to accept and analyze quality measures data, it is necessary that the measures follow a basic and familiar structure. Since we have had experience analyzing PQRS-structured measures, it is necessary to implement restrictions on the structure of measures submitted by qualified clinical data registries. For the reasons stated above and based on the comments received, we are finalizing this requirement, as proposed.

• The outcome and process measures reported must contain numerator data. That is, the upper portion of a fraction used to calculate a rate, proportion, or ratio. The numerator must detail the quality clinical action expected that satisfies the condition(s) and is the focus of the measurement for each patient, procedure, or other unit of measurement established by the denominator (that is, patients who received a particular service or providers that completed a specific outcome/process). We solicited and received the following public comment on this proposal:

<u>Comment</u>: Some commenters generally supported this proposal. The commenters believed that qualified clinical data registries should be free to report on measures that do not conform to the way a PQRS measure is structured (such as requiring that measures contain numerator data).

Response: We appreciate the commenters' support for this proposal. For commenters who believe that the qualified clinical data registries should be free to report on measures that do not conform to the PQRS measure structure, particularly containing numerator data, we agree that there are measures that are not structured like PQRS measures that achieve the same goal as PQRS-structured measures of monitoring processes and outcomes. However, for CMS to be able to accept and analyze quality measures data, it is necessary that the measures follow a basic and familiar structure. Since we have had experience analyzing PQRS-structured measures, it is necessary to implement restrictions on the structure

of measures submitted by qualified clinical data registries. For the reasons stated above and based on the comments received, we are finalizing this requirement, as proposed.

• The qualified clinical data registry must provide denominator exceptions for the measures, where appropriate. That is, those conditions that should remove a patient, procedure or unit of measurement from the denominator of the performance rate only if the numerator criteria are not met. Denominator exceptions allow for adjustment of the calculated score for those providers with higher risk populations. Denominator exceptions allow for the exercise of clinical judgment and should be specifically defined where capturing the information in a structured manner fits the clinical workflow. Generic denominator exception reasons used in measures fall into three general categories: Medical, Patient, or System reasons. We solicited and received the following public comment on this proposal:

<u>Comment</u>: Some commenters generally supported this proposal. The commenters believed that qualified clinical data registries should be free to report on measures that do not conform to the way a PQRS measure is structured.

Response: We appreciate the commenters' support for this proposal. For commenters who believe that the qualified clinical data registries should be free to report on measures that do not conform to the PQRS measure structure, we agree that there are measures that are not structured like PQRS measures that achieve the same goal as PQRS-structured measures of monitoring processes and outcomes. However, for CMS to be able to accept and analyze quality measures data, it is necessary that the measures follow a basic and familiar structure. Since we have had experience analyzing PQRS-structured measures, it is necessary to implement restrictions on the structure of measures submitted by qualified clinical data registries. For the reasons stated above and based on the comments received, we are finalizing this requirement, as proposed.

• The qualified clinical data registry must provide denominator exclusions for the measures for which it will report to CMS, where appropriate. That is, those patients with conditions who should be removed from the measure population and denominator before determining if numerator criteria are met. (For example, Patients with bilateral lower extremity amputations would be listed as a denominator

exclusion for a measure requiring foot exams.) We solicited and received the following public comment on this proposal:

<u>Comment</u>: Some commenters generally supported this proposal. The commenters believed that qualified clinical data registries should be free to report on measures that do not conform to the way a PQRS measure is structured.

Response: We appreciate the commenters' support for this proposal. For commenters who believe that the qualified clinical data registries should be free to report on measures that do not conform to the PQRS measure structure, we agree that there are measures that are not structured like PQRS measures that achieve the same goal as PQRS-structured measures of monitoring processes and outcomes. However, for CMS to be able to accept and analyze quality measures data, it is necessary that the measures follow a basic and familiar structure. Since we have had experience analyzing PQRS-structured measures, it is necessary to implement restrictions on the structure of measures submitted by qualified clinical data registries. For the reasons stated above and based on the comments received, we are finalizing this requirement, as proposed.

• The qualified clinical data registry must provide to CMS descriptions for the measures for which it will report to CMS by no later than March 31, 2014. The descriptions must include: name/title of measures, NQF # (if NQF endorsed), descriptions of the denominator, numerator, and when applicable, denominator exceptions and denominator exclusions of the measure. We solicited and received public comment on this proposal:

Comment: Some commenters generally supported this proposal.

<u>Response</u>: We appreciate the commenters' support for this proposal. For the reasons stated above and based on the comments received, we are finalizing this requirement, as proposed.

We note that last year we introduced the reporting of composite measures in the PQRS measure set. While we have had years of experience analyzing measures structured like traditional PQRS measures, we are only in the initial stages of learning how to analyze composite measures. To the extent that we qualified clinical data registries wish to submit composite measures for reporting for the PQRS,

we are requiring that the qualified clinical data registry calculate the composite score for CMS and provide to CMS the formula used for calculating the composite score. It is necessary that qualified clinical data registries be able to calculate the composite score, as well as provide us with their formula for calculating the score as CMS will likely be unable to analyze the data received on composite measures.

Please note that we are specifying the final requirements we are adopting regarding quality measures for satisfactory participation in a qualified clinical data registry under §414.90(g).

12. PQRS Informal Review

Section 414.90(j) provides that eligible professionals and group practices may request an informal review of the determination that an eligible professional or group practice did not satisfactorily submit data on quality measures under the PQRS. Because we believe it is important to also allow eligible professionals who attempt to satisfactorily participate in a qualified clinical data registry to be able to request an informal review of the determination that the eligible professional satisfactorily participated in a qualified clinical data registry, we proposed to modify §414.90(j) to allow individual eligible professionals who attempt to satisfactorily participate in a qualified clinical data registry the opportunity to request an informal review. We solicited and received public comment on this proposal:

<u>Comment</u>: Several commenters supported our proposal to modify §414.90(j) to allow individual eligible professionals who attempt to satisfactorily participate in a qualified clinical data registry the opportunity to request an informal review.

Response: Based on the commenters' positive feedback and for the reasons we set forth above, we are finalizing this proposal, as proposed. We are therefore modifying newly designated §414.90(m) to specify allowing individual eligible professionals who attempt to satisfactorily participate in a qualified clinical data registry the opportunity to request an informal review.

I. Electronic Health Record (EHR) Incentive Program

The HITECH Act (Title IV of Division B of the ARRA, together with Title XIII of Division A of the ARRA) authorizes incentive payments under Medicare and Medicaid for the adoption and meaningful use of certified EHR technology (CEHRT). Section 1848(o)(2)(B)(iii) of the Act requires that in selecting clinical quality measures (CQMs) for eligible professionals (EPs) to report under the EHR Incentive Program, and in establishing the form and manner of reporting, the Secretary shall seek to avoid redundant or duplicative reporting otherwise required. As such, we have taken steps to establish alignments among various quality reporting and payment programs that include the submission of CQMs.

For CY 2012 and subsequent years, §495.8(a)(2)(ii) requires an EP to successfully report the clinical quality measures selected by CMS to CMS or the states, as applicable, in the form and manner specified by CMS or the states, as applicable. In the EHR Incentive Program Stage 2 Final Rule, we established clinical quality measure reporting options for the Medicare EHR Incentive Program for CY 2014 and subsequent years that include one individual reporting option that aligns with the PQRS's EHR reporting option (77 FR 54058) and two group reporting options that align with the PQRS GPRO and Medicare Shared Savings Program (MSSP) and Pioneer ACOs (77 FR 54076 to 54078). In the CY 2014 PFS proposed rule, we proposed two additional aligned options for EPs to report CQMs for the Medicare EHR Incentive Program for CY 2014 and subsequent years with the intention of minimizing the reporting burden on EPs (78 FR 43479-43481). Please note that, during the comment period following the proposed rule, we received comments that were not related to our specific proposals for the EHR Incentive Program in the CY 2014 PFS proposed rule. While we appreciate the commenters' feedback, these comments will not be specifically addressed in this CY 2014 PFS final rule with comment period, as they are beyond the scope of this rule.

1. Qualified Clinical Data Registry Reporting Option

For purposes of meeting the CQM reporting component of meaningful use for the Medicare EHR Incentive Program for the EHR reporting periods in 2014 and subsequent years, we proposed to allow

EPs to submit CQM information using qualified clinical data registries, according to the proposed definition and requirements for qualified clinical data registries under the PQRS (78 FR 43360). We refer readers to the discussion in the proposed rule for further explanation of the PQRS qualified clinical data registry reporting option and the reasons given in support of our proposals (78 FR 43479).

In addition to the criteria that are ultimately established for PORS, we proposed the following additional criteria that an EP who seeks to report COMs for the Medicare EHR Incentive Program using a qualified clinical data registry must satisfy: (1) the EP must use CEHRT as required under the Medicare EHR Incentive Program; (2) the COMs reported must be included in the Stage 2 final rule (see Table 8, 77 FR 54069) and use the same electronic specifications established for the EHR Incentive Program; (3) report 9 CQMs covering at least 3 domains; (4) if an EP's CEHRT does not contain patient data for at least 9 CQMs covering at least 3 domains, then the EP must report the CQMs for which there is patient data and report the remaining CQMs as "zero denominators" as displayed by the EP's CEHRT; and (5) an EP must have CEHRT that is certified to all of the certification criteria required for COMs, including certification of the qualified clinical data registry itself for the functions it will fulfill (for example, calculation, electronic submission). We noted that these proposed additional criteria are already final policies for the COM reporting options that we established for EPs in the EHR Incentive Program Stage 2 final rule. We referred readers to that final rule for further explanation of the policies related to clinical quality measure reporting under the EHR Incentive Program (77 FR 54049-54089). The electronic specifications for the clinical quality measures can be found at http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/eCOM Library.html.

We proposed the qualified clinical data registry reporting option only for those EPs who are beyond their first year of demonstrating meaningful use (MU). For purposes of avoiding a payment adjustment under Medicare, EPs who are in their first year of demonstrating MU in the year immediately preceding a payment adjustment year must satisfy their CQM reporting requirements by October 1 of such preceding year (for example, by October 1, 2014 to avoid a payment adjustment in 2015). We noted that the proposed qualified clinical data registry reporting option would not enable an EP to meet the

deadline to avoid a payment adjustment because these qualified clinical data registries would be submitting data on CQMs by the last day of February following the 2014 PQRS incentive reporting periods, which would occur after October 1, 2013. Therefore, EPs who are first-time meaningful EHR users must report CQMs via attestation as established in the EHR Incentive Program Stage 2 final rule (77 FR 54050). The reporting periods established in the EHR Incentive Program Stage 2 final rule would continue to apply to EPs who would choose to report CQMs under this proposed qualified clinical data registry reporting option for purposes of the Medicare EHR Incentive Program (77 FR 54049-54051). We noted that this may not satisfy requirements for other quality reporting programs that have established 12-month reporting periods, such as the PQRS.

As EPs are required to use CEHRT under section 1848(o)(2)(A)(iii) of the Act, we proposed that, for the Medicare EHR Incentive Program, an EP who seeks to report using a qualified clinical data registry that meets the criteria established for PQRS must also ensure that the registry selected is certified for the functionality that it is intended to fulfill and is a certified EHR Module that is part of the EP's CEHRT.

We solicited and received the following public comments on these proposals:

Comment: One commenter opposed our general proposal to allow EPs to submit CQM information using qualified clinical data registries, according to the definition and requirements for qualified clinical data registries under the PQRS. The commenter indicated that incorporating a qualified clinical data registry option for the EHR Incentive Program would undermine the integrity of the requirements to meet the CQM component of meaningful use. Specifically, the commenter believed the proposed requirements to participate in a qualified clinical data registry were less stringent than the requirements finalized in the EHR Incentive Program Stage 2 final rule with regard to CQM reporting.

Response: We disagree with the commenter's concerns and do not believe the qualified clinical data registry option would be less stringent than the other reporting options already established in the EHR Incentive Program Stage 2 final rule. To the contrary, as discussed above, we proposed certain additional requirements for EPs who report using a qualified clinical data registry for purposes of the

Medicare EHR Incentive Program, which were established previously for other reporting methods in the EHR Incentive Program Stage 2 final rule, such as the requirement that an EP that reports using a qualified clinical data registry must use a product that is CEHRT.

Comment: Several commenters opposed our proposed requirement to only allow reporting of the CQMs included in the Stage 2 final rule (see Table 8, 77 FR 54069), as well as to use the same electronic specifications established for the EHR Incentive Program. The commenters believed EPs should be allowed to report on measures outside of the CQMs included in the Stage 2 final rule to align with the reporting criteria finalized under the PQRS that allows qualified clinical data registries to report on measures outside the PQRS and EHR Incentive Program measure set.

Response: We understand the commenters' desire to create flexibility in the measures that may be reported under this qualified clinical data registry option.

However, the CQMs selected for the EHR Incentive Program were established in the Stage 2 final rule prior to the passage of the American Taxpayer Relief Act of 2012, and we have not proposed to add additional measures to that set. Therefore, we are finalizing this proposal. Please note that, in addition, as we also finalized for EPs using the qualified clinical data registry reporting mechanism for the PQRS, an EP who chooses to report using a qualified clinical data registry to meet the CQM component of meaningful use in 2014 must report the most recent version (that is, the June 2013 version) of the electronic specification of the measures. The exception to this policy is for the measure CMS140v2, Breast Cancer Hormonal Therapy for Stage IC-IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer (NQF 0387). As explained below, since CMS discovered an error in this measure, EPs reporting this measure must use the December 2012 version of this CQM.

We understand the commenters' desire to allow more flexibility in reporting via a qualified clinical data registry and, in the future, we will work towards developing a more flexible program policies and certification criteria that would allow eCQMs developed by QCDRs to be reported to CMS in future rulemaking.

<u>Comment</u>: The majority of the commenters supported this proposal. Many of these commenters were pleased to see a qualified clinical data registry reporting option for the EHR Incentive Program that aligns with the qualified clinical data registry option for the PQRS.

Response: We appreciate the commenters' positive feedback.

Comment: Some commenters opposed our proposed requirement that an EP who seeks to report using a qualified clinical data registry that meets the criteria established for PQRS must also ensure that the registry selected is certified for the functionality that it is intended to fulfill and is a certified EHR Module that is part of the EP's CEHRT. Some of these commenters believe this requirement would bring the qualified clinical data registry option for the EHR Incentive Program out of alignment with the PQRS qualified clinical data registry option for 2014.

Response: Indeed, this additional requirement departs from the product and vendor requirements for a qualified clinical data registry for the PQRS in 2014. However, as we noted in the CY 2014 PFS proposed rule, under section 1848(o)(2)(A)(iii) of the Act, EPs are required to use CEHRT to submit information on clinical quality measures for the EHR Incentive Program. The 2014 Edition certification criteria established by the ONC set the requirements for certification that cover the functionality needed to "capture and export" (45 CFR 170.314(c)(1)), "import and calculate" (45 CFR 170.314(c)(2)), and for "electronic submission" (45 CFR 170.314(c)(3)) of each CQM that will be reported. In order for the EP's CEHRT to meet these criteria, the qualified clinical data registry would need to test and certify to the functionality that it will fulfill for the EP's CQM reporting, and the qualified clinical data registry's certified module would need to be part of the EP's CEHRT.

After consideration of the public comments received, we are finalizing as proposed our proposal to allow EPs to submit CQM information for purposes of the Medicare EHR Incentive Program beginning with the reporting periods in 2014 using qualified clinical data registries, according to the definition and requirements for qualified clinical data registries under the PQRS discussed in section IV.I. of this final rule with comment period and with the additional criteria for the EHR Incentive Program discussed

above. We are finalizing this reporting option only for EPs who are beyond their first year of demonstrating meaningful use.

The registry will need to be certified for the CQM criteria listed at 45 CFR 170.314(c)(2) ("import and calculate") for each CQM that will be submitted and 45 CFR 170.314(c)(3) ("electronic submission"). EPs will still need to include a certified EHR Module as part of their CEHRT that is certified to the CQM criteria listed at 45 CFR 170.314(c)(1) ("capture and export") for each of the CQMs that would be submitted to CMS for the purposes of meeting the CQM requirements of the Medicare EHR Incentive Program. If the qualified clinical data registry is performing the function of data capture for the CQMs that would be submitted to CMS, then the registry would need to be certified to the "capture and export" criteria listed at 45 CFR 170.314(c)(1)., and the certified EHR Module must be part of the EP's CEHRT. Please note that, similar to what is finalized for the PQRS in this final rule with comment period, a qualified clinical data registry would be required to submit quality measures data in a QRDA-III format as proposed (78 FR 43480) and finalized in this final rule with comment period.

Although we mentioned allowing for submission of quality measures data in a QRDA-I format, we are not finalizing the proposal to allow for submission of quality measures data in a QRDA-I format.

2. Group Reporting Option – Comprehensive Primary Care Initiative

The Comprehensive Primary Care (CPC) Initiative, under the authority of section 3021 of the Affordable Care Act, is a multi-payer initiative fostering collaboration between public and private health care payers to strengthen primary care. Under this initiative, CMS will pay participating primary care practices a care management fee to support enhanced, coordinated services. Simultaneously, participating commercial, State, and other federal insurance plans are also offering support to primary care practices that provide high-quality primary care. There are approximately 500 CPC participants across 7 health care markets in the U.S. More details on the CPC Initiative can be found at http://innovation.cms.gov/initiatives/Comprehensive-Primary-Care-Initiative/index.html.

Under the CPC Initiative, CPC practice sites are required to report to CMS a subset of the CQMs that were selected in the EHR Incentive Program Stage 2 final rule for EPs to report under the EHR

Incentive Program beginning in CY 2014 (77 FR 54069-54075). In a continuing effort to align quality reporting programs and innovation initiatives, we propose to add a group reporting option for CQMs to the Medicare EHR Incentive Program beginning in CY 2014 for EPs who are part of a CPC practice site that successfully submits at least 9 electronically specified CQMs covering 3 domains. We proposed that each of the EPs in the CPC practice site would satisfy the CQM reporting component of meaningful use for the relevant reporting period if the CPC practice site successfully submits and meets the reporting requirements of the CPC Initiative. We proposed that only those EPs who are beyond their first year of demonstrating meaningful use may use this proposed CPC group reporting option, for the reasons explained in the preceding section in regard to avoiding a payment adjustment under Medicare. We proposed that EPs who successfully submit as part of a CPC practice site in accordance with the requirements established for the CPC Initiative and using CEHRT would satisfy their CQM reporting requirement for the Medicare EHR Incentive Program.

If a CPC practice site fails the requirements established for the CPC Initiative, we noted that the EPs who are part of the site would have the opportunity to report CQMs per the requirements and deadlines established in the EHR Incentive Program Stage 2 final rule for EPs to report under the EHR Incentive Program beginning in CY 2014 (77 FR 54049). We invited and received the following public comments on these proposals:

Comment: Commenters generally supported our proposal to add a group reporting option for CQMs for the Medicare EHR Incentive Program beginning in CY 2014 for EPs who are part of a CPC practice site that successfully submits at least 9 electronically specified CQMs covering 3 domains. Commenters were also pleased that, should a CPC practice site fails the requirements established for the CPC Initiative, EPs in the practice site would still have the opportunity to report CQMs per the requirements established in the EHR Incentive Program Stage 2 final rule for EPs to report under the EHR Incentive Program beginning in CY 2014. These commenters are pleased that we are proposing to give these EPs another mechanism by which they can meet their reporting requirements under the EHR

Incentive Program if they do not meet those requirements vis-à-vis their participation in the CPC Initiative.

Response: We appreciate the commenters' support for this proposal. In consideration of the comments received and for the reasons stated previously, we are finalizing a group reporting option for the Medicare EHR Incentive Program, beginning in CY 2014 that is aligned with the CPC Initiative. Under this option, EPs that successfully report at least 9 electronically specified CQMs covering at least 3 domains for the relevant reporting period as part of a CPC practice site in accordance with the requirements established for the CPC Initiative and using CEHRT would satisfy the CQM reporting component of meaningful use for the Medicare EHR Incentive Program. EPs reporting under the aligned group reporting option can only report on CQMs that were selected for the EHR Incentive Program in the Stage 2 final rule. If a CPC practice site is not successful in reporting, EPs who are part of the site would still have the opportunity to report CQMs in accordance with the requirements established for the EHR Incentive Program in the Stage 2 final rule. Additionally, only those EPs who are beyond their first year of demonstrating meaningful use may use this CPC group reporting option. Please note that the CPC practice sites must submit the CQM data in the form and manner required by the CPC Initiative.

Therefore, whether the CPC practice site requires electronic submission or attestation of CQMs, the CPC practice site must submit the CQM data in the form and manner required by the CPC Initiative.

3. Reporting of Electronically Specified Clinical Quality Measures for the Medicare EHR Incentive Program

In the EHR Incentive Program Stage 2 final rule, we finalized the CQMs from which EPs would report beginning in CY 2014 under the EHR Incentive Program (77 FR 54069, Table 8). These CQMs are electronically specified and updated annually to account for issues such as changes in billing and diagnosis codes. The requirements specified in the EHR Incentive Program Stage 2 final rule for EPs to report under the EHR Incentive Program beginning in CY 2014 allow for the reporting of different versions of the CQMs. However, it is not technically feasible for CMS to accept data that is electronically reported according to the specifications of the older versions of the CQMs, including

versions that may be allowed for reporting under the EHR Incentive Program. We stated in the EHR Incentive Program Stage 2 final rule that, consistent with section 1848(o)(2)(B)(ii) of the Act, in the event that the Secretary does not have the capacity to receive CQM data electronically, EPs may continue to report CQM data through attestation (77 FR 54076). Therefore, we proposed that EPs who seek to report CQMs electronically under the Medicare EHR Incentive Program must use the most recent version of the electronic specifications for the CQMs and have CEHRT that is tested and certified to the most recent version of the electronic specifications for the CQMs. For example, for the reporting periods in 2014, EPs who want to report CQM data electronically for purposes of satisfying the quality measure reporting component of meaningful use would be required to use the June 2013 version of the CQMs electronic specifications (available at http://www.cms.gov/Regulations-and-

Guidance/Legislation/EHRIncentivePrograms/eCQM_Library.html) and ensure that their CEHRT has been tested and certified to the June 2013 version of the CQMs for purposes of achieving the CQM component of meaningful use in 2014. EPs who do not wish to report CQMs electronically using the most recent version of the electronic specifications (for example, if their CEHRT has not been certified for that particular version) would be allowed to report CQM data to CMS by attestation for the Medicare EHR Incentive Program.

We invited and received public comments on these proposals:

<u>Comment</u>: Some commenters supported our proposal to allow EPs to report on older versions of the CQM electronic specifications to CMS by attestation for the Medicare EHR Incentive Program.

Response: We appreciate the commenters' support for this proposal.

<u>Comment</u>: Some commenters recommended that, in lieu of requiring that all EPs report the most recent version of the electronic specifications for the CQMs and attest to older versions of the electronic specifications for the CQMs, CMS work with ONC to revise the current development and implementation timeline to ensure one set of measure specifications for all EPs.

Response: In the future, we hope to improve our development and implementation timelines so that all EPs would report on only one version of the CQMs. Unfortunately, at this time, it is not

technically feasible for CMS to modify our development and implementation timelines to achieve this goal in 2014.

<u>Comment</u>: One commenter opposed our proposal to require EPs who seek to report CQMs electronically under the Medicare EHR Incentive Program to use the most recent version of the electronic specifications for the CQMs and have CEHRT that is tested and certified to the most recent version of the electronic specifications for the CQMs, as it creates unnecessary burden on EHR vendors.

Response: We appreciate the commenter's response. We respectfully disagree with the commenter's opposition to require EPs who seek to report CQMs electronically under the Medicare EHR Incentive Program to use the most recent version of the electronic specifications for the CQMs and have CEHRT that is tested and certified to the most recent version of the electronic specifications for the CQMs. We believe it is important for EPs to electronically report the most recent versions of the electronic specifications for the CQMs as updated measure versions correct minor inaccuracies found in prior measure versions. To ensure that CEHRT products can successfully transmit CQM data using the most recent version of the electronic specifications for the CQMs, it is important that the product be tested and certified to the most recent version of the electronic specifications for the CQMs. As noted in the proposed rule, at this time, it is not technically feasible for CMS to accept more than one version of the electronic measure specifications for the CQMs. For these reasons, except for the measure CMS140v2, Breast Cancer Hormonal Therapy for Stage IC-IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer (NQF 0387), we are not accepting older versions of the electronic specifications for the CQMs.

Comment: The majority of commenters supported our proposal to require EPs who seek to report CQMs electronically under the Medicare EHR Incentive Program to use the most recent version of the electronic specifications for the CQMs and have CEHRT that is tested and certified to the most recent version of the electronic specifications for the CQMs. Some commenters had concerns regarding whether there would be sufficient time for EHR technology developers to update their systems and timely distribute the updated CQM versions in a way that would enable EPs to report on the updated versions. A

commenter stated that the 6-month release in June for implementation for reporting in the EHR Incentive Program beginning in January 1, 2014 may not provide enough time for CEHRT systems to be updated. Therefore, the commenter requested that any updates made to measure specifications be minimal. Any major changes to the measure itself, the measure logic, or the value sets would require additional time to address all necessary steps in the implementation process, and should be avoided.

Response: We understand the commenter's concerns regarding the implementation timeline. We agree that any changes to the electronic specifications for the CQMs should be non-substantive. Indeed, please note that, as we noted in the EHR Incentive Program Stage 2 final rule, any substantive changes that will be made to the CQM electronic measure specifications will be non-substantive (77 FR 54055-54056).

Therefore, after consideration of the comments received and for the reasons stated previously, we are finalizing the following proposal: EPs who seek to report CQMs electronically under the Medicare EHR Incentive Program must use the most recent version of the electronic specifications for the CQMs and have CEHRT that is tested and certified to the most recent version of the electronic specifications for the CQMs.

We are also finalizing the policy that EPs who do not wish to report CQMs electronically using the most recent version of the electronic specifications (for example, if their CEHRT has not been certified for that particular version) will be allowed to report CQM data to CMS by attestation for the Medicare EHR Incentive Program. For further explanation of reporting CQMs by attestation, we refer readers to the EHR Incentive Program Stage 1 final rule (77 FR 44430 through 44434) and the EHR Incentive Program's Registration and Attestation page (available at https://ehrincentives.cms.gov/hitech/login.action). Please note that for attestation we are not requiring that products reporting on older versions of the electronic specifications for the CQMs have CEHRT that is tested and certified to the most recent version of the electronic specifications for the CQMs. Rather, if attesting to older versions of the electronic specifications for the CQMs, it is sufficient that the product is CEHRT certified to the 2014 Edition certification criteria.

For the reporting periods in 2014, EPs who want to report CQM data electronically (through a qualified clinical data registry or other product that is CEHRT) to satisfy the quality measure reporting component of meaningful use must use the June 2013 version of the CQMs electronic specifications (available at http://www.cms.gov/Regulations-and-

Guidance/Legislation/EHRIncentivePrograms/eCQM Library.html). CQM data must be submitted using either the QRDA-I or QRDA-III format as finalized in the Stage 2 final rule (77 FR 54076). In addition, EPs must ensure that their CEHRT has been tested and certified to the June 2013 version of the CQMs for purposes of achieving the COM component of meaningful use in 2014. Please note that, for 2014 only, we are providing one exception to this rule for the measure CMS140v2, Breast Cancer Hormonal Therapy for Stage IC-IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer (NQF 0387) because an error was found in the June 2013 logic of this measure. The June 2013 version of this measure was posted on CMS's website on June 29, 2013. The error relates to the relative timing of the diagnosis of breast cancer and the diagnosis of ER or PR positive breast cancer. In clinical practice, a diagnosis of breast cancer should precede the more specific diagnosis of ER or PR positive breast cancer. The logic in CMS140v2 reverses this order. The expected impact of this error is that very few but most likely no patients will meet the denominator criteria. Therefore, if EPs want to report this measure electronically, we are requiring that EPs report on the measure CMS140v1, which is the prior, December 2012 version of the measure CMS140v2, Breast Cancer Hormonal Therapy for Stage IC-IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer (NQF 0387). To the extent that an EP reports another version of this measure other than CMS140v1, (for example, if their certified EHR technology includes the other version), we require EPs to report the other version by attestation. Should an EP report on CMS140v2, the June 2013 version of the measure titled Breast Cancer Hormonal Therapy for Stage IC-IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer (NQF 0387), the EP must report this June 2013 version of the measure by attestation.

4. Reporting Periods in CY 2014

In the Stage 2 final rule, we established the EHR reporting periods in CY 2014 for EPs that have previously demonstrated meaningful use (77 FR 53975). Specifically, we finalized a three-month CY quarter EHR reporting period for 2014, which means that Medicare EPs will attest using an EHR reporting period of January 1, 2014 through March 31, 2014; April 1, 2014 through June 30, 2014; July 1, 2014 through September 30, 2014; or October 1, 2014 through December 31, 2014. We also established the reporting periods for CQMs in CY 2014, which are generally the same as the EHR reporting period (77 FR 54049-54051). Although we did not propose to change these established reporting periods, we understand that there may be instances where an EP may prefer to report COM data for a certain quarter and report the meaningful use objectives and measures for a different quarter. For example, a technical problem could arise for a submission of CQM data that would not affect an EP's submission of meaningful use functional measures, or vice versa. To provide additional flexibility for EPs, we will accept reporting periods of different quarters for CQMs and for meaningful use functional measures, as long as the quarters are within CY 2014. We note that if an EP chooses to use a reporting option for the Medicare EHR Incentive Program that aligns with another CMS quality reporting program, the EP should be mindful of the reporting period required by that program if the EP seeks to meet the quality measure reporting requirements for both the Medicare EHR Incentive Program and the aligned quality reporting program.

J. Medicare Shared Savings Program

Under section 1899 of the Act, CMS has established the Medicare Shared Savings Program (Shared Savings Program) to facilitate coordination and cooperation among providers to improve the quality of care for Medicare Fee-For-Service (FFS) beneficiaries and reduce the rate of growth in healthcare costs. Eligible groups of providers and suppliers, including physicians, hospitals, and other healthcare providers, may participate in the Shared Savings Program by forming or participating in an Accountable Care Organization (ACO). The final rule implementing the Shared Savings Program appeared in the November 2, 2011 **Federal Register** (Medicare Shared Savings Program: Accountable Care Organizations Final Rule (76 FR 67802)).

ACOs are required to completely and accurately report on all quality performance measures for all quality measurement reporting periods in each performance year of their agreement period. There are currently 33 quality performance measures under the Shared Savings Program. For Shared Savings Program ACOs beginning their agreement period in April or July, 2012, there will be two reporting periods in the first performance year, corresponding to calendar years 2012 and 2013. For ACOs beginning their agreement periods in 2013 or later, both the performance year and reporting period will correspond to the calendar year. Reporting on measures associated with a reporting period will generally be done in the spring of the following calendar year. For example, an ACO will submit quality measures for the 2015 reporting period in early 2016.

1. Medicare Shared Savings Program and Physician Quality Reporting System Payment Adjustment Section 1899(b)(3)(D) of the Act affords the Secretary discretion to "* * * incorporate reporting requirements and incentive payments related to the physician quality reporting initiative (PQRI), under section 1848, including such requirements and such payments related to electronic prescribing, electronic health records, and other similar initiatives under section 1848 * * *" and permits the Secretary to "use alternative criteria than would otherwise apply [under section 1848 of the Act] for determining whether to make such payments." Under this authority, we incorporated certain Physician Quality Reporting System (PQRS) reporting requirements and incentive payments into the Shared Savings Program, including: (1)

the 22 GPRO quality measures identified in Table 1 of the final rule (76 FR 67889 through 67890); (2) reporting via the GPRO web interface; (3) criteria for satisfactory reporting; and (4) set January 1 through December 31 as the reporting period. The regulation governing the incorporation of PQRS incentives and reporting requirements under the Shared Savings Program is set forth at §425.504.

Under section 1848(a)(8) of the Act, a payment adjustment will apply under the PORS beginning in 2015 based on quality reporting during the applicable reporting period. Eligible professionals who do not satisfactorily report quality data in 2013 will be subject to a downward payment adjustment applied to the PFS amount for covered professional services furnished by the eligible professional during 2015. For eligible professionals subject to the 2015 PQRSpayment adjustment, the fee schedule amount is equal to 98.5 percent (and 98 percent for 2016 and each subsequent year) of the fee schedule amount that would otherwise apply to such services. To continue to align Shared Savings Program requirements with PQRS, for the 2013 reporting period (which will be used to determine the 2015 PQRS payment adjustment to PFS amounts), in the CY 2013 PFS final rule with comment (77 FR 69372), we amended \$425.504 to include the PQRS reporting requirements necessary for eligible professionals in an ACO to avoid the 2015 PQRS payment adjustment. Specifically, we required ACOs on behalf of eligible professionals that are ACO providers/suppliers to successfully report one ACO GPRO measure in 2013 to avoid the payment adjustment in 2015. We also provided that ACO providers/suppliers that are eligible professionals may only participate under their ACO participant tax identification number (TIN) as a group practice for purposes of avoiding the PQRS payment adjustment in 2015. Thus, ACO providers/suppliers who are eligible professionals may not seek to avoid the payment adjustment by reporting either as individuals under the traditional PQRS or under the traditional PQRS GPRO under their ACO participant TIN. We note, however, that eligible professionals may bill Medicare under more than one TIN (for example, eligible professionals may bill Medicare under a non-ACO participant TIN in one practice location and also bill Medicare under the TIN of an ACO participant at another practice location). As a result, ACO providers/suppliers who are eligible professionals that bill under a non-ACO participant TIN during the year could and should participate under the traditional PQRS as either individual EPs or a

group practice for purposes of avoiding the PQRS payment adjustment for the claims billed under the non-ACO participant TIN. In fact, such EPs would have to do so to avoid the PQRS payment adjustment with respect to those claims because the regulation at §425.504 only applies to claims submitted by ACO providers/suppliers that are eligible professionals billing under an ACO participant TIN. If eligible professionals within an ACO meet the requirements for avoiding the PQRS payment adjustment established under the Shared Savings Program, only the claims billed through the TIN of the ACO participant will avoid the payment adjustment in 2015.

For the 2014 reporting period and subsequent reporting periods (which would apply to the PQRS payment adjustment for 2016 and subsequent payment years), we proposed to align with the requirements for reporting under the traditional PQRS GPRO through the CMS web interface by amending §425.504 to require that ACOs on behalf of their ACO providers/suppliers who are eligible professionals satisfactorily report the 22 ACO GPRO measures during the 2014 and subsequent reporting periods to avoid the PQRS payment adjustment for 2016 and subsequent payment years (78 FR 43482). Additionally, we proposed to continue the current requirement that ACO providers/suppliers who are eligible professionals may only participate under their ACO participant TIN for purposes of the payment adjustment in 2016 and subsequent years.

As we stated in the proposed rule (78 FR 43482), we believe that the proposal to modify the requirements for ACOs to satisfactorily report the 22 ACO GPRO measures to avoid the 2016 payment adjustments would not increase burden on ACOs or on ACO providers/suppliers that are eligible professionals because ACOs must already report these measures in order to satisfy the Shared Savings Program quality performance standard. Thus, this proposal would not increase the total number of measures that must be reported by the ACO and its ACO providers/suppliers that are eligible professionals. We also noted that these proposals would not

affect the Shared Savings Program quality performance standard reporting requirement under which ACOs are currently required to report on 33 quality performance measures, which includes all 22 of the ACO GPRO quality measures.

Comment: We received several comments in favor of continued alignment with PQRS reporting requirements and ongoing efforts to harmonize the program. We received no comments against continued alignment. One commenter said alignment minimizes the additional reporting burden on ACOs and is consistent with ongoing quality initiatives. Another commenter said alignment between programs eases administrative burden. In addition we received some comments about the Pioneer ACO Model's alignment with PQRS that are out of the scope of this proposed rule. We have shared these comments with our colleagues in the Innovation Center. In addition, two commenters stated that when a physician leaves an ACO, the ACO should not be responsible for reporting quality measures for that physician.

Response: We appreciate the comments in support of our proposal, and for the reasons discussed above and in the proposed rule, we are finalizing our proposal to align with PQRS GPRO web interface reporting requirements, finalized elsewhere in this PFS, for eligible professionals (EPs) and their participant TINs in ACOs to avoid the payment adjustment in 2016 and subsequent years. We are also finalizing our proposal to add a new paragraph (c) to the regulation at \$425.504 to reflect these reporting requirements for 2016 and subsequent years. Although we are finalizing this policy as proposed, we have made some technical corrections to the text and formatting of \$425.504(c) in order to remove inconsistent language that was inadvertently included in this provision as it appeared in the proposed rule. With respect to the comments about changes in the ACO participants and ACO providers/suppliers and the effect on ACO quality reporting, these issues are are out of the scope of this rule. We note, however, that we have addressed the effect of changes in ACO participants on ACO quality reporting in subregulatory guidance available at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-

Payment/sharedsavingsprogram/Updating-ACO-Participant-List.html. Additionally, ACOs are required

to report certain measures using the GPRO web interface tool. Specifically, §425.504(a)(1) and (b)(1) require that ACOs submit quality measures using the GPRO web interface to qualify on behalf of their eligible professionals for the PQRS incentive or to avoid the PQRS payment adjustment. This reporting mechanism is also referenced in §425.308(e), which provides that quality measures that ACOs report using the GPRO web interface will be reported by CMS on the Physician Compare website.

Under §414.90(h)(3)(i), group practices may report data under the traditional PQRS GPRO through a CMS web interface. The Shared Savings Program regulations at §425.504(a)(1) and (b)(1) and §425.308(e) specifically reference the use of the GPRO web interface for quality reporting purposes. We proposed to amend these regulations to replace references to GPRO web interface with CMS web interface. We believe this change will ensure consistency with the reporting mechanism used under §414.90(h)(3)(i) and will also allow for the flexibility to use a similar web interface in the event that operational issues are encountered with the use of the GPRO web interface. We invited public comment on this proposal.

<u>Comment</u>: We did not receive direct comments against broadening our reference to the web interface; however, one commenter expressed concern that the suggested change signaled that CMS intends to change the reporting mechanism and the commenter opposed any change in reporting mechanism saying, it took time and resources to learn the current reporting mechanism.

Response: We are finalizing our proposal to use the more broad term CMS web interface to align with PQRS, and are also finalizing the proposed revisions to our regulations at §§ 425.308(e) and 425.504(a)(1) and (b)(1) to reflect this change. We would like to reassure Shared Saving Program ACOs that we do not currently have plans to change the reporting mechanism for Shared Savings Program ACOs from the GPRO web interface. However, broadening the term to "CMS web interface" aligns with PQRS and gives CMS the flexibility to use an alternative web interface in the event that PQRS requirements change or operational issues with the GPRO web interface adversely impact ACO quality reporting.

We also received a comment making suggestions about the reporting mechanism used under the Pioneer ACO Model. This comment is out of the scope of the proposed rule, but we have shared the comment with our colleagues in the Innovation Center.

2. Medicare Shared Savings Program-Establishing the Quality Performance Benchmark

Section 1899(b)(3)(C) of the Act directs the Secretary to "* * *establish quality performance standards to assess the quality of care furnished by ACOs * * * " and to "improve the quality of care furnished by ACOs over time by specifying higher standards, new measures, or both for purposes of assessing such quality of care." In the Shared Savings Program final rule, we finalized the following requirements with regard to establishing a performance benchmark for measures: (1) During the first performance year for an ACO, the quality performance standard is set at the level of complete and accurate reporting; (2) during subsequent performance years, the quality performance standard will be phased in such that ACOs will be assessed on their performance on each measure; (3) CMS designates a performance benchmark and minimum attainment level for each measure, and establishes a point scale for the measures; and (4) contingent upon data availability, performance benchmarks are defined by CMS based on national Medicare fee-for-service rates, national Medicare Advantage (MA) quality measure rates, or a national flat percentage. In the final rule, we indicated that we would not compare an ACO's quality performance to the performance of other ACOs for purposes of determining an ACO's overall quality score. We acknowledged, however, that in future program years, we should seek to incorporate actual ACO performance on quality measures into the quality benchmarks after seeking industry input through rulemaking.

a. Data Sources Used to Establish Performance Benchmarks

The regulation governing the data that CMS will use to establish the performance benchmarks for quality performance measures under the Shared Savings Program is set forth at §425.502(b)(2). This provision states that CMS will define the performance benchmarks based on national Medicare fee-for-service rates, national MA quality measure rates, or a national flat percentage. In the Shared Savings Program final rule, we responded to comments suggesting that quality performance benchmarks be set

based on actual historical data submitted by ACOs. We stated that although we agreed that we should seek to incorporate actual ACO performance on quality scores into the quality benchmark, we would do so only in future rulemaking so that we could seek industry input. In addition, we noted that we expected to update the quality benchmarks over time, consistent with section 1899(b)(3)(C) of the Act, which requires CMS to seek to improve the quality of care furnished by ACOs participating in the Shared Savings Program over time.

Consistent with our stated intention to incorporate actual ACO experience into quality measure benchmarks, for the 2014 reporting period, we proposed to amend §425.502(b)(2) to permit CMS to use all available and applicable national Medicare Advantage and Medicare FFS performance data to set the quality performance benchmarks. Specifically, in addition to using available national Medicare FFS rates, which include data reported through PORS, and national MA quality measure rates, we proposed to use data submitted by Shared Savings Program and Pioneer ACOs in 2013 for the 2012 reporting period to set the performance benchmarks for the 2014 reporting period. We proposed to publish the quality benchmarks based upon these data prior to the beginning of the 2014 reporting period through subregulatory guidance. As stated in the Shared Savings Program final rule, we establish benchmarks using the most currently available data source and the most recent available year of benchmark data prior to the start of the reporting period. In other words, data collected in 2014 from the 2013 reporting period would be used in conjunction with other available data to set benchmarks for the 2015 reporting period, and so on. We proposed to retain the option of using flat percentages when data are unavailable, inadequate or unreliable to set quality performance benchmarks. Further, we clarified our intent to combine data derived from national Medicare Advantage and national Medicare FFS to set performance benchmarks when the measure specifications used under Medicare Advantage and FFS Medicare are the same. We proposed to revise §425.502(b)(2)(i) to reflect this clarification. We solicited comment on these proposals, and whether there are other data sources that should be considered in setting performance benchmarks.

Comment: We received a generally favorable response to incorporating ACO data into setting the benchmarks, and a few commenters supported using all available data, including ACO data, to establish benchmarks; one commenter in favor of using all data stated more data are better for setting benchmarks, and including ACO data emphasizes that CMS expects all providers to improve quality. However, most commenters opposed the proposal to use ACO data alone when no other data were available to set benchmarks, stating that they believed that when only ACO data were available it would unfairly narrow the data set. They stated that ACOs should be assessed against the broader FFS population instead of only against themselves. A few commenters stated that culture and the socioeconomic status of some patient populations could adversely affect scoring for these organizations if they were compared only to other ACOs, particularly on the CAHPS measures, and that each community and its resources and characteristics should be taken into account when establishing benchmarks, including rewarding ACOs on the basis of individual improvement. Similarly, other commenters felt that using ACO data alone would inflate the benchmarks and make them unattainable to new ACOs entering into the program the following year. A few commenters suggested that CMS not move to pay for performance, but rather continue pay for reporting when there are only ACO data available to set the benchmark. One commenter stated "Among [Pioneer] ACOs, some metrics had a wide variation of interpretation that resulted in a bimodal distribution. When there is such a bimodal distribution, separate benchmarks should be used based on [ACO] interpretation [of the measure] - higher benchmarks for wide interpretation, lower benchmarks for stricter interpretation.... We recommend that benchmarks be based only on the subset of data consistent with the [ACO] interpretation that was chosen." When data other than ACO data are available, many commenters were opposed to combining it with MA data, stating that the structure of the MA program, with closed networks and the opt-in of beneficiaries, enables MA plans to attain higher performance scores. Some commenters also stated it was not fair to include PQRS GPRO data in developing quality performance benchmarks for ACOs because groups reporting under the PORS GPRO are more advanced or integrated organizations that have multiple years of experience in collecting and reporting medical record data.

On the other hand, regarding use of flat percentages, one of the commenters said flat percentages should never be used. Another commenter suggested that flat percentages should only be used if the 60th percentile had a value of 70 percent or greater, particularly in relation to measures that are clustered. A commenter suggested starting with a flat percentage that is lower than actual ACO data, and then increasing the benchmark as more data become available in order to measure and reward ACO improvement over time.

Regarding our proposal to set benchmarks yearly based on the previous year's ACO reporting, a commenter expressed concern about fluctuating benchmarks in the event that CMS finalized its proposal to set benchmarks yearly based on the previous year's ACO data submission. Commenters noted that such a policy may unfairly disadvantage ACOs joining the program, particularly when only ACO data are available to set benchmarks.

Response: We are finalizing our proposal to use fee-for-service data, including data submitted by Shared Savings Program and Pioneer ACOs to set the performance benchmarks for the 2014 and subsequent reporting periods. Although we continue to believe it is appropriate to combine data from MA and PQRS reporting when the quality measure specifications are the same, or to use MA data when FFS data are unavailable, we are swayed by commenters who request that in light of the different structure of the MA program, we reconsider using MA data to set benchmarks in the early stages of the program. Therefore, we will not finalize our proposal to use MA data alone or in combination with fee-for-service data in the short-term. We intend to revisit the policy of using MA data in future rulemaking when we have more experience setting benchmarks for ACOs. However, we are finalizing our proposal to combine all available Medicare fee-for-service quality data, including data gathered under PQRS (through both the GPRO tool and other quality reporting mechanisms). We continue to believe that it is appropriate to use PQRS GPRO data to set benchmarks because the measure specifications are the same and are submitted by FFS providers. We do not agree with commenters who suggested that PQRS GPROs have an unfair advantage over other providers because PQRS GPROs range in size and capability. Nor do we agree with commenters that recommended setting benchmarks that take into

consideration ACO interpretation of measure specifications. The GPRO web interface and measure specifications, as well as education on how to report the measures, are equally available to all Medicare enrolled providers, and the measure specifications are not subject to ACO interpretation.

Finally, we recognize the concerns raised by commenters that setting benchmarks based on ACO data alone, particularly in the early years of the Shared Savings Program, could result in punishing relatively high performers for quality measures where performance is high among most ACOs. Additionally, we appreciate the suggestions by commenters who incorporated our proposed de-clustering methodology on when and how to use flat percentages to reward high performance. We are finalizing an approach that makes use of a combination of actual data and flat percentages; specifically, we will use all available FFS data to calculate benchmarks, including ACO data, except where performance at the 60th percentile is equal to or greater than 80 percent for individual measures, regardless of whether or not the measure is clustered. In these cases, a flat percentage will be used to set the benchmark for the measure. By way of example, please refer to Table 81. This policy allows ACOs with high scores to earn maximum or near maximum quality points while allowing room for improvement and rewarding that improvement in subsequent years. We chose 80 percent because this level of attainment indicates a high level of performance and we believe ACOs achieving an 80 percent performance rate should not be penalized as low performers.

Trible of viction of year in setting benefitial its using that percentages											
Percentile	30 th	40 th	50 th	60 th	70 th	80 th	90 th				
Performance rates using all available FFS	85.83	86.21	86.76	87.15	87.65	88.21	89.23				
data											
Revised benchmark using flat percentages when the 60 th percentile is 80 percent or	30.00	40.00	50.00	60.00	70.00	80.00	90.00				
more.											
Quality points earned by the ACO**	1.10	1.25	1.40	1.55	1.70	1.85	2.0				

TABLE 81: Methodology for setting benchmarks using flat percentages

Example is for illustration purposes only and is not based on actual data

We are also finalizing our proposal to set benchmarks prior to the reporting year for which they would apply. Specifically, we are finalizing our proposal to set the quality performance benchmarks for the 2014 reporting period using data submitted in 2013 for the 2012 reporting period. We will publish the quality performance benchmarks for the 2014 reporting period through subregulatory guidance. However, we are not finalizing our proposal to modify the benchmarks on a yearly basis. We recognize commenters' concerns that for some measures in the first few years, we will only have a limited amount of data which may cause benchmarks to fluctuate in early program years, making it difficult for ACOs to improve upon their previous year's performance. Instead, we will set the benchmarks for the 2014 reporting year in advance using data submitted in 2013 for the 2012 reporting year, and continue to use those benchmarks for 2 reporting years (specifically, the 2014 and 2015 reporting years). We intend to readdress this issue in future rulemaking to allow for public comment on the appropriate number of years before updating benchmarks going forward. We have revised the regulation at §425.502(b)(2) to reflect these final policies with respect to defining the quality benchmarks.

b. Ensuring Meaningful Differences in Performance Rates

Data collected by CMS from the GPRO and Physician Group Practice Demonstration participants in 2012 coupled with previous CMS experience indicates that using actual data to calculate quality

^{**}Note: points are double the points shown here for the EHR measure.

performance may result in some measures' performance rates being tightly clustered. In this case, quality scores for the measure may not reflect clinically meaningful differences between the performance rates achieved by reporters of quality. For example, for some measures, the distribution of performance rates may have a spread of less than 2.0 percentage points between the 30th and 90th percentiles. In such an instance, even though there is little distinction in actual performance rates, a slight difference in performance on the measure may result in a significant difference in the number of quality points obtained under the Shared Savings Program. For example, two separate ACOs at the 50th percentile and the 90th percentile may have only a few tenths of a percentage point difference in their actual performance, but under the Shared Savings Program scoring methodology, the difference between their quality scores for that measure would be more noteworthy (1.4 points versus 2.0 points).

We continue to believe it is desirable to use performance rates for measures based on actual data because doing this creates benchmarks that are simple to understand and apply, even if the rates are clustered, as the data reflect achievable performance on quality measures. However, allowing clustered performance rates for a measure may result in payment differences that are not associated with clinically meaningful differences in patient care, as noted in the example above.

Keeping these issues in mind, we proposed to develop a methodology to spread clustered performance on measures. The first step in developing that methodology is to identify when performance on a measure is clustered. Clustering could be defined as less than a certain spread between performance rates in an identified range; for example, less than 6.0 percentage points between the performance rates associated with the 30th and 90th percentiles, or less than 10.0 percentage points between the minimum and maximum values achieved by previous reporters of the quality measure. Alternatively, clustering could be defined as a spread of performance rates of less than x percentage points between any two deciles, for example, less than a 1.0 percentage point difference between the 60th and 70th decile.

Once a clustered measure has been identified, the next step is to apply a methodology to spread or separate the performance rates within the measure. It is important to establish a meaningful performance rate, or starting point, around which to differentiate or spread the performance. For example, selecting a

certain percentile or median value may represent one option for establishing a reasonable starting point. Once the starting point is set, then we could implement a series of fixed percentage point intervals around the starting point in both a positive and negative direction to increase the spread, for example, applying a fixed 1.0 percentage point interval between scored deciles. For example, if the starting point is the 60th percentile, and the performance rates at the 60th and 70th percentiles were observed to be 77.15 and 77.65 respectively, there would be only a 0.5 spread between the deciles. In contrast, applying a fixed 1.0 percentage point interval to increase spread would result in a 1.0 difference between these rates, and the new performance rates would be 77.15 and 78.15 at the 60th and 70th percentiles, respectively. In the alternative, we could take the spread calculated from a subset (for example, ACO performance only) of the underlying performance data if we believe that data reported by ACOs show a different variability than other data sources. For example, the spread between the measure's percentiles could be based on historical ACO distribution only, not the historical distribution of Medicare Advantage and/or national fee-for-service, PQRS, and ACO data. The historical ACO distribution could then be applied to the Medicare Advantage and/or national fee-for-service, PQRS, and ACO percentile distribution to establish the measure's percentiles.

In the proposed rule, we stated that we believe that a clinically meaningful assessment of ACO quality is important. We also noted that we are interested in providing a pathway for ACOs new to quality reporting to achieve the quality reporting standard, and an incentive for experienced ACOs to continue improving and performing at high levels. We therefore proposed to use a standardized method for calculating benchmark rates when a measure's performance rates are tightly clustered. We proposed that the application of a methodology to reduce measure clustering would only apply to quality measures whose performance rates are calculated as percentiles, that is, the methodology would not apply to measures whose performance rates are calculated as ratios, for example, measures such as the two ACO Ambulatory Sensitive Conditions Admissions and the All Condition Readmission measure. We believe that measures whose performance rates are calculated as ratios already demonstrate a high degree of

clinically meaningful differences because they are risk adjusted to reflect the health status of the patient population being measured.

We proposed to define a tightly clustered measure, including clinical process and outcome measures reported through the GPRO web interface and CAHPS measures, as one that demonstrates less than a 6.0 percentage point spread in performance rates between the 30th and 90th percentiles. As discussed in the proposed rule, we believe using the 30th and 90th percentiles as the lower and upper bounds is reasonable because these bounds have been given some significance in earlier rulemaking; specifically, the Shared Savings Program regulations set the ACO's minimum attainment level at the 30th percentile, below which the ACO achieves no points, and the ACO achieves full points for quality reporting at or above the 90th percentile. Further, we proposed to establish the starting point at the 60th percentile, the midpoint between the 30th and 90th percentiles, and then to apply a positive 1.0 fixed percentage point interval for each decile above the 60th percentile and a negative 1.0 fixed percentage point interval for each decile below the 60th percentile.

We recognized that spreading tightly clustered performance measures would decrease the lower bound necessary to meet the minimum attainment level for the measure, giving ACOs new to quality reporting a greater opportunity to meet the quality performance standard. At the same time, spreading tightly clustered performance rates would increase the upper bound necessary for achieving the maximum available quality points for the measure, giving already experienced ACOs an incentive to continue improving quality. Applying a 1.0 fixed percentage point interval achieves the goal of creating meaningful differences in performance. Further, we stated that we believe that applying a 1.0 fixed percentage point interval represents a tempered and reasonable interval that does not spread performance rates to levels that are too easy to achieve on the lower bound or too difficult to achieve on the upper bound.

For example, Table 82 demonstrates the original spread of a quality measure, based on all available data, which is compressed from a range of 75.83 at the 30th percentile to 79.23 at the 90th percentile, that is, a spread of less than 6.0 percentage points. When the proposed methodology is

applied, the 60th percentile (or 77.15 percent), serving as the starting point, remains unchanged. The spread increases 6.0 percentage points from 74.15 at the 30th percentile to 80.15 at the 90th percentile. As demonstrated and explained above, this methodology improves the distinction in performance between the minimum attainment level (30th percentile) and the maximum attainment level (90th percentile).

TABLE 82: Proposed Methodology to Reduce Clustered Performance Rates

Percentile	30 th	40 th	50 th	60 th	70 th	80 th	90 th
Original performance rates using all	75.83	76.21	76.76	77.15	77.65	78.21	79.23
available data							
Performance rates using methodology to	74.15	75.15	76.15	77.15	78.15	79.15	80.15
reduce clustering							

^{*}Example is for illustration purposes only and is not based on actual data

We proposed to amend §425.502(b) to reflect this methodology to reduce clustering. We solicited comment on these proposals. Specifically, we sought comment on whether or not a methodology should be applied to spread out clustered performance on measures. We also solicited comment on the proposal to define clustered performance on a measure as one in which the spread of performance rates between the 30th and 90th percentiles is less than 6.0 percentage points, or whether other values should be used to define clustered measure performance, for example, when the minimum and maximum reported values are spread by less than 10.0 percentage points. We also solicited comment on whether there are alternative methodologies that should be considered to spread out clustered performance on measures. In addition, we solicited comment on whether measures that are calculated as ratios should be excluded from this methodology. We also requested comment on whether all available relevant data should be considered when developing the spread between measures, or whether only the relevant performance data from a subset of reporters, such as ACO-reported data, as discussed above, should be used to determine the appropriate spread between deciles.

<u>Comment</u>: We received many comments against creating a larger spread when quality measure benchmarks are clustered. No commenters were in favor of spreading benchmarks when they are clustered. Alternatives proposed by commenters were to continue pay for reporting when the scores are clustered, or to develop a methodology that rewards improvement in individual ACO quality scores and to structure points to reward "positive outliers" when scores are clustered at the lower scores. A

commenter said, "While there may not be a significant spread for comparison, those entities that do perform at a relatively close level of quality performance should be recognized for their actual level of performance." A commenter suggested considering approaches that are not threshold- and benchmark-based, but instead reward every single instance when correct care was provided. Another commenter suggested using fewer points of differentiation such as quartile scores rather than decile scores for clustered measures. A commenter suggested CMS adopt a methodology that rewards all the good performing programs and further rewards the excellent "best practices." A commenter suggested using a flat percentage if the 60th percentile value is above an absolute rate of 70 percent as an alternate approach to addressing tightly clustered measures.

Response: We appreciate the comments and suggestions for alternatives for addressing tightly clustered measures. We are not finalizing the proposal to create a spread when benchmarks are tightly clustered. We are convinced by commenters who said that spreading benchmarks could create artificial clinically meaningful differences in quality reporting and payment, particularly when underlying performance relative to peers would remain unchanged. However, we reserve the right to revisit this issue in future rulemaking when we have more experience and data.

Instead, we will use the method described above which will take into account actual ACO performance on measures by using FFS data (including ACO and PQRS reported data) where available to set benchmarks except where performance at the 60th percentile is equal to or greater than 80 percent, in which case, flat percentages will be used to set the benchmark. We chose this threshold for the reasons noted above. This method will both reduce clustering for these measures and reward ACOs for actual performance. Additionally, as we move toward using ACO data to set benchmarks, we will continue to consider how clustering of measures intersects with our ability to determine both an appropriate minimum standard for a quality measure as

well as how the overall performance on that measure is scored for the ACO, or whether these concepts should be decoupled.

Finally, in response to comments on alternative explicit ways to reward improvement, we note that the Shared Savings Program methodology rewards organizations with a greater share of savings for higher quality performance in pay for performance years; however, we will continue to consider this issue and may address it further in future rulemaking.

c. Scoring CAHPS Measures Within the Patient Experience of Care Domain

The preamble to the Shared Savings Program final rule (76 FR 67895-67900) outlines the total potential points available per domain as demonstrated in Table 83. As indicated in Table 83, under the final rule the Patient/Caregiver Experience Domain is weighted equally with the other three quality domains at 25 percent and consists of 2 measures: a composite of six Clinician and Group (CG) CAHPS summary survey measures (1) Getting Timely Care, Appointments and Information, (2) How Well Your Doctors Communicate, (3) Patient's Rating of Doctor, (4) Access to Specialists, (5) Health Promotion and Education, (6) Shared Decision Making, and a Health Status/Functional Status measure. The six measures included in the composite will transition to pay-for-performance starting in the second year of an ACO's agreement period. In contrast, the Health Status/Functional Status measure will remain pay-for-reporting throughout the ACO's entire agreement period.

TABLE 83: Total Points for Each Domain within the Quality Performance Standard

Domain	Total Individual Measures (Table F1)	Total Measures for Scoring Purposes	Total Potential Points Per Domain	Domain Weight
Patient/Caregiver Experience	7	1 measure, with 6 survey module measures combined, plus 1 individual measure	4	25%
Care Coordination/ Patient Safety	6	6 measures, plus the EHR measure double- weighted (4 points)	14	25%
Preventative Health	8	8 measures	16	25%
At Risk Population	12	7 measures, including 5 component diabetes composite measure and 2 component CAD composite measure	14	25%

Domain	Total Individual Measures (Table F1)	Total Measures for Scoring Purposes	Total Potential Points Per Domain	Domain Weight
Total	33	23	48	100%

^{*}from Table 4 in the Shared Savings Program Final Rule (76 FR 67899)

The result of this point system is that performance on the six patient experience measures is worth only 12.5 percent of an ACO's total performance score because the other 12.5 percent of the Patient/Caregiver Experience domain is the Health Status/Functional Status measure, which is a pay-for-reporting measure for all performance years. However, as we stated in the proposed rule, we believe that each of these seven measures is equally important within the Patient/Caregiver Experience domain, and that scoring within the domain should better reflect performance on these measures, thereby placing a greater emphasis on the voice of the patient through patient-reported outcomes and experiences. We believe that increasing the weight of the 6 measures that will become pay-for-performance in the second year of the agreement period will incentivize ACOs to improve their performance on these measures. A policy to place a greater emphasis on patient-reported outcomes and experiences is consistent with our goal to improve the quality of care furnished by ACOs over time.

Therefore, we proposed to modify the point scoring for the Patient/Caregiver Experience domain as demonstrated in Table 84. As modified, each of the 7 survey module measures within the domain would be assigned a maximum value of 2 points. The Patient/Caregiver Experience domain would then be worth a total of 14 points, rather than 4 points. The end result would be that each of the 7 measure modules in the domain would have equal weight. We noted that this change would not affect the

weighting of the domain itself in relationship to the other three domains; it would remain 25 percent of the ACO's total quality performance score.

TABLE 84: Modified Total Points for Each Domain within the Quality Performance Standard

Domain	Total Individual Measures (Table F1)	Total Measures for Scoring Purposes	Total Potential Points Per Domain	Domain Weight
Patient/Caregiver Experience	7	7 individual survey module measures	14	25%
Care Coordination/ Patient Safety	6	6 measures, plus the EHR measure double-weighted (4 points)	14	25%
Preventative Health	8	8 measures	16	25%
At Risk Population	12	7 measures, including 5 component diabetes composite measure and 2 component CAD composite measure	14	25%
Total	33	28	58	100%

We stated that we believe giving equal weight to each of the Patient/Caregiver Experience measures modules is appropriate because it places greater emphasis on patient-reported experiences, promotes clinically meaningful differences in ACO performance within the domain, and is consistent with the statutory mandate to improve quality of care furnished by ACOs over time. The proposed change would also bring the total points for the domain in line with the points available in other domains.

We solicited comments on our proposal to modify the point scoring within the Patient/Caregiver Experience domain.

<u>Comment</u>: A majority of comments received were in support of reweighting the CAHPS measure modules. Commenters stated that assigning each measure module equal weight would be consistent with the patient centric goals of the ACO program. We received two comments against reweighting before the end of the first ACO agreement period. These commenters stated that the weighting should remain as it is

to allow ACOs to "cement this capability." Finally, a commenter made the comment that the CAHPS data is not timely or actionable.

Response: We appreciate the comments in support of reweighting the CAHPS measure module scoring and, for the reasons discussed above and in the proposed rule, are finalizing our proposal to assign 2 points to each of the 6 CAHPS survey measure modules (12 points) instead of scoring them as one component worth only two points. Reweighting will take effect for the 2014 reporting period for all Shared Savings Program ACOs and will increase the value of the patient experience of care domain from 4 points to 14 points and result in the six survey measure module in the patient experience of care survey accounting for 86 percent of the domain score. We note that the overall domain's weight would remain the same in relation to the other three domains, and therefore do not believe this reweighting will impact an ACO's ability to 'cement' its capabilities. Finally, we disagree that the information gathered from the patient experience of care survey is not actionable. The survey results, in conjunction with information derived from the ACO's process to promote internal cost and quality reporting, as required under the Shared Savings Program regulations, can be used by ACOs to identify areas for improvement, monitor care for its patient population, and improve, as well as measure the ACO's performance in this domain.

K. Value-Based Payment Modifier and Physician Feedback Program

1. Overview

Section 1848(p) of the Act requires that we establish a value-based payment modifier and apply it to specific physicians and groups of physicians the Secretary determines appropriate starting January 1, 2015 and to all physicians and groups of physicians by January 1, 2017. On or after January 1, 2017, section 1848(p)(7) of the Act provides the Secretary discretion to apply the value-based payment modifier to eligible professionals as defined in section 1848(k)(3)(B) of the Act. Section 1848(p)(4)(C) of the Act requires the value-based payment modifier to be budget neutral.

In this final rule with comment period, we are finalizing our proposed policies to continue to phase in implementation of the value-based payment modifier by applying it to smaller groups of physicians and to increase the amount of payment at risk. We also are finalizing our proposals to refine the methodologies used in our quality-tiering approach to calculating the value-based payment modifier in order to better identify both high and low performers for upward and downward payment adjustments. We note two changes from our proposals that we are finalizing after considering the public comments we received. First, we are adopting a single plurality attribution approach for the Medicare Spending per Beneficiary cost measure rather than the proposed multiple attribution approach. Second, we are adopting a threshold of 50 percent (rather than the proposed 70 percent) for the percentage of individual eligible professionals in a group of physicians that must meet the criteria to avoid the CY 2016 PQRS payment adjustment in order to calculate a group quality score.

2. Governing Principles for Physician Value-Based Payment Modifier Implementation.

In the CY 2013 PFS final rule with comment period (77 FR 69306), we stated that the value-based payment modifier has the potential to help transform Medicare from a passive payer to an active purchaser of higher quality, more efficient and more effective healthcare by providing upward payment adjustments under the PFS to high performing physicians (and groups of physicians) and downward adjustments for low performing physicians (and groups of physicians). We also noted that Medicare is implementing value-based payment adjustments for other types of services, including inpatient hospital

services. Further, in implementing value-based purchasing initiatives generally, we seek to recognize and reward high quality care and quality improvements, and to promote more efficient and effective care through the use of evidence-based measures, the reduction in administrative burden and duplication, and less fragmented care.

In the CY 2013 PFS final rule with comment period, we established that the following specific principles should govern the implementation of the value-based payment modifier (77 FR 69307).

- A focus on measurement and alignment. Measures for the value-based payment modifier should consistently reflect differences in performance among physicians and physician groups, reflect the diversity of services furnished, and be consistent with the National Quality Strategy and other CMS quality initiatives, including the PQRS, the Medicare Shared Savings Program, and the Medicare EHR Incentive Program.
- A focus on physician choice. Physicians should be able to choose the level (individual or group) at which their quality performance will be assessed, reflecting physicians' choice over their practice configurations. The choice of level should align with the requirements of other physician quality reporting programs.
- A focus on shared accountability. The value-based payment modifier can facilitate shared
 accountability by assessing performance at the group practice level and by focusing on the total costs of
 care, not just the costs of care furnished by an individual physician.
- A focus on actionable information. The Quality and Resource Use Reports (QRURs) should provide meaningful and actionable information to help groups of physicians and physicians identify clinical areas where they are doing well, as well as areas in which performance could be improved by providing groups of physicians with QRURs on the quality and cost of care they furnish to their patients.
- A focus on a gradual implementation. The value-based payment modifier should focus initially on identifying high and low performing groups of physicians. Moreover, groups of physicians should be able to elect how the value-based payment modifier would apply to their payment under the PFS starting in CY 2015. As we gain more experience with physician measurement tools and

methodologies, we can broaden the scope of measures assessed, refine physician peer groups, create finer payment distinctions, and provide greater payment incentives for high performance.

3. Overview of Existing Policies for the Physician Value-Based Payment Modifier.

In the CY 2013 PFS final rule with comment period, we finalized policies to phase-in the value-based payment modifier by applying it starting January 1, 2015 to payments under the Medicare PFS for physicians in groups of 100 or more eligible professionals. A summary of the existing policies that we finalized for the CY 2015 value-based payment modifier can be found in the proposed rule (78 FR 43486 through 43488).

4. Provisions of this Final Rule with Comment Period

We proposed additions and refinements to the existing value-based payment modifier policies. Specifically, the proposed rule included the following proposals:

- To apply the value-based payment modifier to groups of physicians with 10 or more eligible professionals in CY 2016.
- To make quality-tiering mandatory for groups within Category 1 for the CY 2016 value-based payment modifier, except that groups of physicians with between 10 and 99 eligible professionals would be subject only to any upward or neutral adjustment determined under the quality-tiering methodology, and groups of physicians with 100 or more eligible professionals would be subject to upward, neutral, or downward adjustments determined under the quality-tiering methodology.
- To increase the amount of payment at risk under the value-based payment modifier from 1.0 percent to 2.0 percent in CY 2016.
- To align the quality measures and quality reporting mechanisms for the value-based payment modifier with those available to groups of physicians under the PQRS during the CY 2014 performance period.
- To include the Medicare Spending Per Beneficiary (MSPB) measure in the total per capita costs for all attributed beneficiaries domain of the cost composite.

• To refine the cost measure benchmarking methodology to account for the specialties of the physicians in the group.

In this final rule with comment period, we discuss each of the proposed policies, the comments received, our responses to the comments, and a brief statement of our final policy.

a. Group Size

In the CY 2013 PFS final rule with comment period, we stated that we would gradually phase in the value-based payment modifier in CY 2015 by first applying it to large groups (77 FR 69308), which we defined as groups of physicians with 100 or more eligible professionals. We noted our view that it would be reasonable to focus on groups with 100 or more eligible professionals before expanding the application of the value-based payment modifier to more groups and solo practitioners in CY 2016 and beyond.

To continue our phase-in of the value-based payment modifier, we proposed to apply the value-based payment modifier in CY 2016 to groups of physicians with 10 or more eligible professionals. We estimated that this proposal would apply to approximately 17,000 groups (TINs) and nearly 60 percent of physicians under the value-based payment modifier in CY 2016. We believed this proposal would continue our policy to phase in the value-based payment modifier by ensuring that the majority of physicians are covered in CY 2016 before it applies to all physicians in CY 2017. Given the results of the statistical reliability analyses on the PQRS quality measures and the cost measures contained in the 2010 and 2011 groups and individual QRURs (78 FR 43500 through 43502), we stated that we believed we can reliably apply a value-based payment modifier to groups of physicians with 10 or more eligible professionals in CY 2016 and to smaller groups and to solo practitioners in future years. Accordingly, we proposed to revise the regulations at §414.1210 to reflect that the CY 2016 value-based payment modifier would be applicable to physicians that are in groups with 10 or more eligible professionals. We solicited comments on this proposal.

The following is a summary of the comments we received regarding this proposal.

<u>Comment</u>: Several commenters supported our proposal to apply the value-based payment modifier to groups of 10 or more eligible professionals in 2016. Some commenters indicated that the proposed phased approach for increasing the number of physicians to which the value-based payment modifier applies was appropriate since the statute requires that the value-based payment modifier apply to all physicians in 2017.

Many commenters were opposed to our proposed policy. Some of these commenters stated that broadening the implementation of the value-based payment modifier to groups of 10 or more eligible professionals so quickly is premature because CMS did not have the opportunity to assess the impact on smaller groups, while others stated that implementation of the value-based payment modifier should be delayed until CMS can assure the accuracy and consistency of performance scoring. Some commenters were concerned about whether the groups that are currently subject to the value-based payment modifier have enough Medicare patients to ensure that cost and quality variation is truly measuring differences in performance rather than random risks. Commenters also noted that more than 10,500 groups will be 8 or 9 months into their first performance year before they see one of the confidential QRURs that are the key to CMS' value-based payment modifier outreach and education campaign. Other commenters suggested that there were too few subspecialist measures in the PQRS and that it would mean that small to mid-size groups would not have sufficient measures to be successful in the PQRS. Other commenters stated that groups of physicians with between 10 and 24 EPs would not have a QRUR until the summer of 2014 and thus should not be subject to the value-based payment modifier. Some commenters indicated that the value-based payment modifier is yet another regulatory burden as they transition to ICD-10. Still other comments objected to the entire concept of the value-based payment modifier and urged us not to implement it. Several commenters suggested that we apply the value-based payment modifier to groups of 25 or more eligible professionals or to groups of 50 or more eligible professionals.

Response: Our focus as we gradually implement the value-based payment modifier is to increase quality measurement, because without measurement we do not believe that we can have consistent and sustained quality of care improvements for Medicare FFS beneficiaries. Furthermore, our approach to

apply the value-based payment modifier to groups of 10 or more EPs is consistent with our principle to focus on a gradual implementation of the value-based payment modifier. Therefore, we disagree with commenters' suggestions that we not finalize our proposal to apply the value-based payment modifier to groups of 10 or more EPs, or that we instead apply the value-based payment modifier to groups of 25 or more EPs or 50 or more EPs, because this would delay improving quality of care furnished by groups of 10 or more EPs to FFS beneficiaries. We also continue to believe that we can validly and reliably apply a value-based payment modifier to groups of physicians with 10 or more eligible professionals in CY 2016 because we will be basing the quality score on the measures selected, and reported on, by the group of physicians or the individual EPs in the group. In addition, as discussed below, we are including an additional cost measure in the value-based payment modifier (the Medicare Spending per Beneficiary measure) and are adjusting our cost comparison approach to consider the medical specialty composition of the group of physicians.

Moreover, based on an analysis of our CY 2012 QRURs that we made available to groups of 25 or more eligible professionals on September 16, 2013, the PQRS quality measures and the cost measures used for the value-based payment modifier have high average statistical reliability. High statistical reliability in this context means we would arrive at consistent results under similar conditions. Moreover, these findings corroborate the findings from our group and individual CY 2010 and 2011 QRURs (78 FR 43500 through 43502) that found high reliability among the measures used for the value-based payment modifier. We found that the PQRS quality measures, even those reported at the individual level, were reliable; therefore, we believe that the PQRS quality measures for groups of 10 or more EPs will also be reliable. Further, because we use a minimum case size of 20 in order for a quality or cost measure to be included in the quality of care or cost composites of the value-based payment modifier, we believe that the composites will not only be valid, but also statistically reliable. Therefore, we disagree with the commenters' concerns about the statistical reliability of the PQRS quality measure performance rates. Furthermore, we will continue to monitor the value-based payment modifier program and continue to examine the characteristic of those groups of physicians that could be subject to an upward or downward

payment adjustment under our quality-tiering methodology to determine whether our policies create anomalous effects in ways that do not reflect consistent differences in performance among physicians and physician groups.

In the CY 2012 QRURs, we attributed, on average, 3007 beneficiaries to groups of 25 or more EPs. Moreover, approximately 65 percent of primary care services received by attributed beneficiaries were rendered by physicians in the group. Therefore, we do not agree with commenters' concerns about whether groups subject to the value-based payment modifier have enough Medicare patients to ensure that the variation in cost and quality is measuring differences in performance rather than random risk. And, as noted above, we also use a minimum case size of 20 when including quality and cost measures in the quality of care and cost composites of the value-based payment modifier.

Several commenters expressed concern regarding the number of PQRS measures applicable to subspecialists and suggested that small to mid-size groups do not have a sufficient number of measures in the PQRS to report. For purposes of the value-based payment modifier, we will use the performance on those measures that are reported through the PQRS reporting mechanisms adopted for the value-based payment modifier, even if fewer than three measures are reported, to calculate a group of physicians' quality composite score so long as the group of physicians (or at least 50 percent of the EPs in the group, if reporting as individuals under the PQRS) meet the criteria to avoid the 2016 PQRS payment adjustment. As discussed above in section H.4, we are modifying some of the satisfactory critieria for the 2016 PQRS payment adjustment that we believe addresses this concern so that such physicians will not be adversely affected under the value-based payment modifier.

In response to the commenters who objected to applying the value-based payment modifier to groups of 10 or more eligible professionals because groups of 10-24 eligible professionals have not seen how they would fare under the value-based payment modifier because they will not have a QRUR until midway through the CY 2014 performance period, we note that in the late summer of 2014, we plan to disseminate QRURs based on CY 2013 data to all physicians (that is, TINs of any size). These QRURs will contain performance information on the quality and cost measures used to score the quality and cost

composites of the value-based payment modifier and will show how all TINs would fare under the value-based payment modifier policies finalized in this final rule with comment period. Please note that as discussed in section III.K.4.b. below, we are also finalizing our proposed policy to hold harmless groups with 10-99 eligible professionals from any downward payment adjustments under quality-tiering in CY 2016, thus shielding these groups from any downward payment adjustments in 2016.

<u>Comment:</u> Several commenters recommended that CMS reconsider its decision to exclude Accountable Care Organizations (ACOs) from the value-based payment modifier. These commenters indicated that ACOs should have the opportunity to be rewarded for their practice to the extent these groups provide high quality and, low cost care. Commenters recommended that ACOs be permitted to optionally participate in the value-based payment modifier or that CMS should provide a plan for addressing how innovators participating in the Medicare ACO programs will be affected by the value-based payment modifier.

Response: We finalized in the CY 2013 PFS final rule with comment period (77 FR 69313) that we will not apply the value-based payment modifier in CY 2015 and CY 2016 to groups of physicians that are participating in the Medicare Shared Savings Program Accountable Care Organizations (ACOs), the testing of the Pioneer ACO model, the Comprehensive Primary Care Initiative, or other similar Innovation Center or CMS initiatives. From an operational perspective, we will apply this policy to any group of physicians that otherwise would be subject to the value-based payment modifier, if one or more physician(s) in the group participate(s) in one of these programs or initiatives during the relevant performance period (CY 2013 for the CY 2015 value-based payment modifier, and CY 2014 for the CY 2016 value-based payment modifier). We will take these comments into consideration as we develop proposals for the value-based payment modifier and ACOs in future years.

After consideration of the comments received and for the reasons stated previously, we are finalizing that the value-based payment modifier will apply to groups of physicians with 10 or more eligible professionals in CY 2016.

We proposed to identify groups of physicians that would be subject to the value-based payment modifier (for example, for CY 2016, groups of physicians with 10 or more eligible professionals) using the same procedures that we finalized in the CY 2013 PFS final rule with comment period (for a description of those procedures, we refer readers to 77 FR 69309 through 69310). Rather than querying Medicare's PECOS data base as of October 15 or another date certain, however, we proposed to perform the query within 10 days of the close of the PQRS group self-nomination/registration process during the relevant performance period year. We proposed to revise the regulations at §414.1210(c) to reflect that identification of the groups of physicians subject to the value-based payment modifier is based on a query of PECOS at the close of the PQRS registration period and that groups of physicians are removed from this list if, based on a claims analysis, the group of physicians did not have the required number of eligible professionals, as defined in §414.1210(a), that submitted claims during the performance period for the applicable calendar year payment adjustment period. We solicited comment on this proposal.

We did not receive any comments on this proposal; therefore, we are finalizing this proposal without modification.

b. Approach to Setting the Value-Based Payment Modifier Adjustment Based on PQRS Participation

In the CY 2013 PFS final rule with comment period (77 FR 69311), we adopted a policy to categorize groups of physicians subject to the value-based payment modifier in CY 2015 based on a group's participation in the PQRS. Specifically, we categorize groups of physicians eligible for the CY 2015 value-based payment modifier into two categories. Category 1 includes groups that either (a) self-nominate for the PQRS as a group and report at least one measure or (b) elect the PQRS Administrative Claims option as a group for CY 2013. Groups of physicians in Category 1 may elect to have their value-based payment modifier for CY 2015 calculated using the quality-tiering methodology, which could result in an upward, neutral, or downward adjustment amount. The value-based payment modifier for groups of physicians in Category 1 that do not elect quality tiering is 0.0 percent, meaning that physicians in these groups will not receive a payment adjustment under the value-based payment

modifier for CY 2015. Category 2 includes groups of physicians that do not fall within Category 1. For those groups of physicians in Category 2, the value-based payment modifier for CY 2015 is -1.0 percent.

We proposed to use a similar two-category approach for the CY 2016 value-based payment modifier based on a group of physicians' participation in the PQRS but with different criteria for inclusion in Category 1 (78 FR 43489 through 43490). Category 2 would include those groups of physicians that are subject to the CY 2016 value-based payment modifier and do not fall within Category 1. Our proposal was intended to accommodate the various ways in which physicians can participate in the PORS in CY 2014 – either as a group practice participating in the PORS GPRO or individually. We established in the CY 2013 PFS final rule with comment period that groups of physicians that wish to participate as a group in the PQRS during CY 2014 must self-nominate and select one of three PQRS GPRO reporting mechanisms: GPRO web interface, qualified registry, or EHR (77 FR 69199-69200 (Table 93)). We also established the criteria for satisfactory reporting of data on PQRS quality measures via the GPRO for the PORS payment adjustment for CY 2016 (77 FR 69200-69202), and we proposed to modify these criteria as described in Table 27 of the CY 2014 PFS proposed rule (78 FR 43370). In order to maintain alignment with the PQRS, for purposes of the CY 2016 value-based payment modifier, we proposed that Category 1 would include those groups of physicians that meet the criteria for satisfactory reporting of data on PQRS quality measures via the GPRO (through use of the web-interface, EHRs, or qualified registry reporting mechanisms) for the CY 2016 PQRS payment adjustment.

We explained in the CY 2014 PFS proposed rule (78 FR 43489-43490) that not all groups of physicians may want to participate in PQRS as a group under the GPRO in CY 2014. These groups of physicians may prefer to have all of their eligible professionals continue to report PQRS measures as individuals so that physicians and other eligible professionals in the group are able to report data on quality measures that reflect their own clinical practice. In addition, eligible professionals in these groups of physicians may wish to use different reporting mechanisms to report data for PQRS, such as the claims-based reporting mechanism, EHRs, qualified registries, or the proposed qualified clinical data registry reporting mechanism. Therefore, for the CY 2016 value-based payment modifier, we proposed to

include in Category 1 groups of physicians that do not self-nominate to participate in the PQRS as a group practice in CY 2014 and that have at least 70 percent of the group's eligible professionals meet the criteria for satisfactory reporting of data on PQRS quality measures as individuals for the CY 2016 PQRS payment adjustment, or in lieu of satisfactory reporting, satisfactorily participate in a PQRS-qualified clinical data registry for the CY 2016 PQRS payment adjustment. Our intention with this proposal was to align the criteria for inclusion in Category 1 with the criteria that are established for the CY 2016 PQRS payment adjustment.

We also proposed to revise the regulation text at §414.1225, which was previously specific to the CY 2013 performance period and only referred to quality measures reported by groups of physicians rather than individual eligible professionals within a group. We solicited comment on these proposals. The following is summary of the comments we received regarding these proposals.

Comment: The vast majority of commenters supported our proposal to continue to align the value-based payment modifier with the PQRS reporting mechanisms and to place groups of physicians into two categories for purposes of the value-based payment modifier based upon PQRS participation. Several commenters suggested that such alignment was essential to reduce physician burden. Other commenters highlighted the importance of physicians continuing to have the option to select the clinical quality measures via PQRS (and the appropriate reporting mechanism) that will be used for the calculation of the value-based payment modifier.

Response: We appreciate commenters' support for our proposals. One of the principles governing our implementation of the value-based payment modifier is to align program requirements to the extent possible. Thus, we expect to continue to align the value-based payment modifier with the PQRS program requirements and reporting mechanisms to ensure physicians and groups of physicians report data on quality measures that reflect their practice. We appreciate commenters' support for our continuation of the two category approach that we proposed for the CY 2016 value-based payment modifier.

Comment: Many commenters supported our proposal to include in Category 1 groups of physicians that do not participate in the PQRS as a group practice in CY 2014 but who have at least 70 percent of the group's EPs meet the criteria for satisfactory reporting of data on PQRS quality measures as individuals for the CY 2016 PQRS payment adjustment, or in lieu of satisfactory reporting, satisfactorily participate in a PORS-qualified clinical data registry for the CY 2016 payment adjustment. Commenters suggested this proposal is essential for those small group practices that do not participate in the PQRS GPRO and whose individual EPs have reported via the claims reporting mechanism for the past several years. Several commenters, however, suggested that we lower the proposed 70 percent threshold to 50 percent so that more groups can fall into Category 1 through reporting at the individual level. Several commenters supported a lower threshold because of (a) the increased reporting thresholds to avoid the 2016 PQRS payment adjustment, (b) the minimal participation in the PQRS GPRO, which would make this option more attractive, (c) lack of measures for certain sub-specialists that practice in smaller groups, and (d) the transition to ICD-10. One commenter suggested that we utilize a tiered approach by setting the threshold at 25 percent in the first year, 50 percent in the second year, and 75 percent in the third year (and thereafter) in order to allow more groups to be successful in reporting under this option.

Response: We appreciate commenters' support for our proposal to provide a way to combine individually reported PQRS measures into a group score for purposes of the CY 2016 value-based payment modifier. We believe that the value-based payment modifier should recognize the diversity of physician practices and the various measures used to assess quality of care furnished by these practices.

We are persuaded, however, by commenters' suggestion to lower the 70 percent threshold to 50 percent for many of the reasons the commenters stated. We expect to propose in future rulemaking to raise the 50 percent threshold in order to provide a more comprehensive assessment of the quality of care furnished by a group of physicians across a richer set of quality dimensions.

By setting the threshold to 50 percent, we estimate that 76 percent of groups of physicians with between 10 and 19 EPs (based on 2011 PQRS participation) would meet the 50 percent threshold and 45 percent of groups with 100 or more EPs would meet the 50 percent threshold.

Accordingly, we are finalizing our proposal to align the criteria for inclusion in Category 1 with the criteria for the CY 2016 PORS payment adjustment as referenced above in PORS Tables 48 and 50, which show the criteria to avoid the CY 2016 PQRS payment adjustment for group practices reporting through the GPRO and individual EPs. For the CY 2016 value-based payment modifier, Category 1 will include those groups of physicians that meet the criteria for satisfactory reporting of data on PORS quality measures through the GPRO for the CY 2016 PQRS payment adjustment. Category 1 will also include those groups of physicians that do not register to participate in the PQRS as a group practice in CY 2014 and that have at least 50 percent of the group's eligible professionals meet the criteria for satisfactory reporting of data on PQRS quality measures as individuals for the CY 2016 PQRS payment adjustment, or in lieu of satisfactory reporting, satisfactorily participate in a PORS-qualified clinical data registry for the CY 2016 PQRS payment adjustment. For a group of physicians that is subject to the CY 2016 valuebased payment modifier to be included in Category 1, the criteria for satisfactory reporting (or the criteria for satisfactory participation, in the case of the 50 percent option) must be met during the CY 2014 performance period for the PQRS CY 2016 payment adjustment. Category 2 will include those groups of physicians that are subject to the CY 2016 value-based payment modifier and do not fall within Category 1. We also are finalizing our proposed revisions to the regulation text at §414.1225, which was previously specific to the CY 2013 performance period and only referred to quality measures reported by groups of physicians rather than individual eligible professionals within a group.

We proposed to more fully phase-in the quality-tiering methodology for calculating the value-based payment modifier for CY 2016 based on the number of eligible professionals in the group. We proposed that groups in Category 1 would no longer have the option to elect quality tiering for the CY 2016 value-based payment modifier (as was the case for the CY 2015 value-based payment modifier) and instead would be subject to mandatory quality tiering. We proposed to apply the quality-tiering

methodology to all groups in Category 1 for the value-based payment modifier for CY 2016, except that groups of physicians with between 10 and 99 eligible professionals would be subject only to upward or neutral adjustments derived under the quality-tiering methodology, while groups of physicians with 100 or more eligible professionals would be subject to upward, neutral, or downward adjustments derived under the quality-tiering methodology. In other words, we proposed that groups of physicians in Category 1 with between 10 and 99 eligible professionals would be held harmless from any downward adjustments derived from the quality-tiering methodology for the CY 2016 value-based payment modifier. We stated our belief that this proposed approach would reward groups of physicians that provide high-quality/low-cost care, reduce program complexity, and more fully engage groups of physicians in our plans to implement the value-based payment modifier. Accordingly, we proposed to revise the regulations at §414.1270 to reflect the proposal to make the quality-tiering methodology mandatory, with the exception noted above, for all groups of physicians subject to the value-based payment modifier in CY 2016 that fall within Category 1. We solicited comment on this proposal.

Comment: Many commenters opposed this proposal for the following reasons: (1) the proposed new PQRS quality reporting mechanisms and requirements for 2014 make it difficult for groups (as identified by the Taxpayer Identification Number (TIN)) to estimate their quality score; (2) the lack of a PQRS aggregate reporting mechanism makes it difficult for medical groups that use multiple TINs to bill Medicare to report on all of its TINs using one reporting mechanism; (3) groups of 100 or more do not yet understand how their cost composites would change given our proposals to add a new cost measure (MSPB) and to change our peer group methodology; (4) groups of 100 or more have not yet seen their 2012 Quality and Resource Use Report, (available September 16, 2013), and which contains how they would fare under the quality-tiering methodology; and (5) not enough time to understand the impact of the new beneficiary attribution method used in the reports and then to use the patient level data in the 2012 QRURs to improve performance before the next performance period (CY 2014).

Some commenters supported the proposal and suggested that the only way to truly drive quality improvements in the health care delivery system was to measure performance on quality measures and to

attach payment consequences to that performance. Several commenters urged us to move away from the "pay for reporting" approach that we had adopted for the value-based payment modifier for CY 2015.

Response: We are not persuaded by commenters' concerns with our proposal to require mandatory quality tiering for calculating the value-based payment modifier for CY 2016 and exempt groups of physicians with between 10 and 99 EPs from any downward adjustments derived under the quality-tiering methodology. Based on an analysis of the CY 2012 QRURs that we made available to groups of 25 or more eligible professionals on September 16, 2013, over 80 percent of 3,876 groups for which we could compute both a quality and cost composite score were classified as average quality and average cost, meaning no payment adjustment under the quality-tiering methodology. Slightly over 8 percent of groups of 25 or more EPs would be classified in tiers that would earn an upward adjustment (11 percent of such groups would earn an additional bonus for treating high-risk beneficiaries) and slightly less than 11 percent of groups of 25 or more EPs would be classified in tiers that would involve a downward payment adjustment. Moreover, for the 1,236 groups of 100 or more eligible professionals based on 2012 data, 68 groups would earn an upward adjustments (with 10 groups earning the additional bonus for treating high-risk beneficiaries) and 88 groups would receive a downward adjustment using the quality-tiering methodology. These results suggest that our quality-tiering methodology identifies a small number of groups of physicians that are outliers – both high and low performers – in terms of whose payments would be affected by the value-based payment modifier, thus limiting any widespread unintended consequences. In addition, we are adopting policies in this final rule to address certain aspects of our previously established methodologies so that beginning in CY 2016 we better assess the group of physicians' quality of care furnished or the cost of that care. These policies include our refinement of the cost composite peer group methodology and the use of PQRS quality data reported by individual EPs. As explained above in section III.K.4.a, we will continue to monitor the value-based payment modifier program and continue to examine the characteristics of those groups of physicians that could be subject to an upward or downward payment adjustment under our quality-tiering methodology

to determine whether our policies create anomalous effects in ways that do not reflect consistent differences in performance among physicians and physician groups.

To address commenters' specific concerns about mandatory quality tiering, we believe groups of physicians will report data for quality measures under PQRS on which they expect their performance would be high, regardless of whether it is a new reporting mechanism or the reporting requirements may have changed for CY 2014. Thus, we disagree with the assertion that groups of physicians must receive a QRUR from CMS before they can understand their performance on quality measures on which they choose to report data. Notwithstanding this observation, the PQRS since 2007 has provided feedback reports to physicians on their performance on reported quality measures so that physicians can see how they compare against others who report the same measures. We also disagree with commenters who suggest that we do not have a quality reporting system that allows large health systems that use multiple TINs to bill Medicare to use one method. The Medicare Shared Savings Program provides a way for large systems (a) to use one reporting mechanism that aggregates their multiple TINs into one organization, (b) to fulfill their PQRS obligations, and (c) to earn savings for furnishing high quality / low cost care.

Further, on September 16, 2013, we made available to all groups of 25 or more EPs an annual QRUR based on 2012 data to help groups estimate their quality and cost composites, thus groups of 100 ore more eligible professionals have had access to their reports. Moreover, these reports provide beneficiary specific information, including hospitalization information for attributed beneficiaries that enables groups of physicians to examine which beneficiaries are driving performance on quality outcome measures and the cost measures. We intend to provide QRURs to all groups of physicians and solo practitioners during the summer of 2014 (based on 2013 performance) that include their performance on the MSPB measure and the new peer group methodologies. Thus, we believe all groups of 100 or more have, or will soon have, the data necessary to begin to improve performance. Although we are sensitive to providing groups of physicians with adequate lead time to understand the impact of the beneficiary attribution method used for the value-baed payment modifier, we believe our policy of holding groups of

between 10 and 99 EPs harmless from any downward payment adjustment would likely mitigate unintended consequences that could occur. In addition, the attributed beneficiaries in the 2012 QRURs had, on average, at least three primary care services furnished by physicians in the group. We believe such information could help groups of physicians estimate which beneficiaries in their patient population may be attributed to them prior to receiving a QRUR that includes data from the relevant performance period.

Comment: Many commenters appreciated the policy to hold harmless groups of physicians with between 10 and 99 EPs from any negative payment adjustments and supported our proposal. A few commenters suggested that applying the value-based payment modifier negative payment adjustment only to groups of 100 or more EPs is an unjust payment methodology because CMS is not holding smaller group practices to the same quality standards as larger group practices. Several commenters also suggested that by eliminating the negative payment adjustment for small group practices, CMS is decreasing the maximum incentive amount a high quality/low cost large group practice could receive under the quality-tiering approach.

Response: We appreciate commenters' support for our proposal. Our focus as we implement the value-based payment modifier is to increase quality measurement, because without measurement we do not believe that we can have consistent and sustained quality of care improvements for Medicare FFS beneficiaries. Large groups practices are more likely to have the ability and means to track and monitor quality of care and resource use whereas many smaller groups are now just developing these capabilities. Thus, we believe it is appropriate to hold groups of physicians with between 10 and 99 EPs harmless from any downward adjustments, which is similar to the policy we are applying to groups of 100 or more EPs during the first year the value-based payment modifier applies to them (2015). We recognize that until the value-based payment modifier is fully implemented, with both upside and downside adjustment applied to all groups of physicians and solo practitioners, we will have disparate impacts and the pool of money available for upward adjustments will be reduced. We believe, however, this policy is consistent

with our overall approach to gradually phase in the value-based payment modifier and reinforces our goal to increase quality reporting while not increasing reporting burdens on physicians.

For these reasons, we are finalizing our proposal that groups of physicians in Category 1 will not have the option to elect quality tiering for the CY 2016 value-based payment modifier and instead will be subject to mandatory quality tiering. We also are finalizing our proposal that groups of physicians in Category 1 with between 10 and 99 eligible professionals will be held harmless from any downward adjustments derived from the quality-tiering methodology for the CY 2016 value-based payment modifier. We are also finalizing the revision to the regulations at §414.1270 to clarify that for the CY 2015 payment adjustment period a group may be determined under the quality-tiering methodology to have low performance based on low quality and high costs, low quality and average costs, or average quality and high costs.

c. Payment Adjustment Amount

Section 1848(p) of the Act does not specify the amount of payment that should be subject to the adjustment for the value-based payment modifier; however, section 1848(p)(4)(C) of the Act requires the value-based payment modifier be implemented in a budget neutral manner. Budget neutrality means that payments will increase for some groups of physicians based on high performance and decrease for others based on low performance, but the aggregate amount of Medicare spending in any given year for physicians' services will not change as a result of application of the value-based payment modifier.

In the CY 2013 PFS final rule with comment period, we adopted a modest payment reduction of 1.0 percent for groups of physicians in Category 1 that elected quality tiering and were classified as low quality/high cost and for groups of physicians in Category 2 (77 FR 69323-24).

As discussed in the CY 2014 proposed rule (78 FR 43500 through 43502), we conducted statistical reliability analysis on the PQRS quality measures and the cost measures contained in the 2010 and 2011 group and individual QRURs. These QRURs contained the quality measures that were reported under the PQRS and five per capita cost measures that we will use for the value-based payment modifier. The quality and cost measures in the group QRURs were very statistically reliable. Moreover, the

average reliability was high for 98 percent of the individually reported PORS measures and for all of the cost measures (with a case size of at least 20) included in the individual QRURs. Thus, we noted our belief that we can increase the amount of payment at risk because we can reliably apply a value-based payment modifier in CY 2016 to groups of physicians with 10 or more eligible professionals and to smaller groups and to solo practitioners in future years. Therefore, we proposed to increase the downward adjustment under the value-based payment modifier from 1.0 percent in CY 2015 to 2.0 percent for CY 2016. That is, for CY 2016, a -2.0 percent value-based payment modifier would apply to groups of physicians subject to the value-based payment modifier that fall in Category 2. In addition, we proposed to increase the maximum downward adjustment under the quality-tiering methodology to -2.0 percent for groups of physicians classified as low quality/high cost and to set the adjustment to -1.0 percent for groups classified as either low quality/average cost or average quality/high cost. We proposed to revise §414.1270 and §414.1275(c) and (d) to reflect the proposed increase to a 2.0 percent adjustment under the value-based payment modifier for the CY 2016 payment adjustment period. We also made a technical correction to §414.1275(c) to clarify the PQRS GPRO reporting mechanisms available in CY 2013. Table 85 shows the proposed quality-tiering payment adjustment amounts for CY 2016 (based on CY 2014 performance).

Table 85: 2016 Value-Based Payment Modifier Amounts

CY 2016					
Cost/Quality	Low quality	Average quality	High quality		
Low cost	+0.0%	+1.0x*	+2.0x*		
Average cost	-1.0%	+0.0%	+1.0x*		
High cost	-2.0%	-1.0%	+0.0%		

^{*} Groups of physicians eligible for an additional +1.0x if reporting Physician Quality Reporting System quality measures and average beneficiary risk score is in the top 25 percent of all beneficiary risk scores.

Consistent with the policy adopted in the CY 2013 PFS final rule with comment period, the upward payment adjustment factor ("x") would be determined after the performance period has ended based on the aggregate amount of downward payment adjustments. We noted that any funds derived from the application of the downward adjustments to groups of physicians with 100 or more eligible

professionals and the downward 2.0 percent adjustment applied to those groups of physicians subject to the value-based payment modifier that fall in Category 2, would be available to all groups of physicians eligible for value-based payment modifier upward payment adjustments. The quality-tiering methodology would continue to provide an additional upward payment adjustment of +1.0x to groups of physicians that care for high-risk beneficiaries (as evidenced by the average HCC risk score of the attributed beneficiary population). We solicited comments on our proposal to increase the downward value-based payment modifier to 2.0 percent for those groups of physicians with 10 or more eligible professionals that are in Category 2 and for groups of physicians with 100 or more eligible professionals that are classified as low quality/high cost groups for the CY 2016 payment adjustment period.

The following is summary of the comments we received regarding this proposal.

Comment: A number of commenters supported our proposal to increase the amount of payment at risk under the value-based payment modifier in CY 2016. Some commenters stated that the payment adjustment must be of significant weight in order to drive physician behavior toward achieving high quality and low cost care. A few commenters suggested that the value-based payment modifier should represent a larger percentage of physician payments under the PFS and stated that the amount of the payment differential should be closer to 10.0 percent, increased incrementally from 2.0 percent and subject to annual review.

Many commenters, however, were opposed to our proposed policy. Several commenters suggested that CMS should not increase the amount of payment at risk under the value-based payment modifier in CY 2016 and recommended keeping the amounts at the CY 2015 levels. A few commenters urged CMS to delay increasing the maximum downward adjustment under the program until at least CY 2017 to allow CMS to gain experience with applying the value-based payment modifier to a broader variety of groups, and to allow physician groups to increase their understanding of their performance under quality-tiering. Some commenters suggested keeping

the downward adjustments for groups subject to the value-based payment modifier at -1.0 percent during the first year and then increasing it to -2.0 percent during the second year. Some commenters indicated that groups that report data and choose to elect quality-tiering should not be at the same risk as groups that did not report at all. Some commenters also indicated that a large number of physicians could see both a two percent PQRS and a two percent value-based payment modifier adjustment in 2016, and when added to a potential two percent sequester reduction, and possibly another two percent EHR adjustment, this could push some older physicians to retire or close their practices to Medicare patients. One commenter indicated that it does not agree that the size of PQRS and value-based payment modifier adjustments is the driving factor in physicians' decisions on whether to participate in these incentive programs.

Response: We agree with the commenters who stated that the amount of payment at risk should be higher than the 1.0 percent amount of payment at risk in 2015 in order to incentivize physicians to provide high quality and low cost care. Our experience under PQRS has shown us that a 1.0 or 2.0 percent incentive payment was insufficient to obtain widespread participation in the PQRS, thus, we believe that we need to increase the amount of payment at risk for the CY 2016 value-based payment modifier in order to incentivize physicians and groups of physicians to report PQRS data, which will be used to calculate the value-based payment modifier.

Therefore, we are finalizing our proposal to increase the maximum downward adjustment for the CY 2016 value-based payment modifier to 2.0 percent for those groups of physicians with 10 or more eligible professionals that are in Category 2 and for groups of physicians with 100 or more eligible professionals that are in Category 1 and are classified as low quality/high cost groups. We also believe that our final policy, as described above in section III.K.4.b, to calculate for a group of physicians the performance on PORS quality measures reported by individual eligible

professionals in the group will enable more groups to fall under Category 1 and avoid Category 2's automatic -2.0 percent payment adjustment. Even though several commenters suggested that we increase incrementally the amount of payment at risk to 10 percent, we believe that it is premature in this final rule with comment period to lay out the roadmap for future years as suggested by these commenters.

After consideration of the comments received and for the reasons stated previously, we are finalizing our proposed policies as described above.

d. Performance Period

In the CY 2013 PFS final rule with comment period (77 FR 69314), we adopted a policy that performance on quality and cost measures in CY 2014 will be used to calculate the value-based payment modifier that is applied to items and services for which payment is made under the PFS during CY 2016. We received comments in response to the CY 2013 PFS proposed rule requesting that we close the gap between the end of the performance period (for example, December 31, 2014) and the beginning of the payment adjustment period (for example, January 1, 2016), in order to strengthen the connection between the performance of physicians and groups of physicians and the financial incentives for quality improvement.³ We understand that many private sector plans start to provide payment adjustment within 7 months of close of the performance period.⁴

Since the payment adjustment periods for the value-based payment modifier are tied to the PFS, which is updated on an annual calendar year basis, options to close the 1-year gap between the close of the performance period and the start of the payment adjustment period are

³ See, e.g., Comment of the American College of Surgeons comment on the CY 2013 PFS proposed rule (Aug. 31, 2012).

⁴ US GAO, Medicare Physician Payment: Private-Sector Initiatives Can Help Inform CMS Quality and Efficiency Incentive Efforts, GAO-13-160 (Dec. 2012), available at http://www.gao.gov/assets/660/651102.pdf.

limited and primarily are centered around altering the start and end dates of the performance period. As discussed previously in section III.H. of this final rule with comment period, one option could be to adjust the performance period for quality data reported through the PQRS. In addition, we could calculate the total per capita cost measures on an April 1 through March 31 basis, thus closing the gap by 3 months.

However, a byproduct of altering the performance periods is that the deadline for submitting quality information would have to occur promptly at the end of the performance period. In addition, the review period during which groups of physicians will be able to review the calculation of the value-based payment modifier would be shortened to allow the necessary system changes to implement the adjustment by the January 1 deadline for implementation of the annual PFS. We solicited comment on the potential merits of altering our current performance periods.

We proposed to use CY 2015 as the performance period for the value-based payment modifier adjustments that will apply during CY 2017. We believe it is important to propose the performance period for the payment adjustments that will apply in CY 2017, because section 1848(p)(4)(B)(iii) of the Act requires all physicians and groups of physicians to be subject to the value-based payment modifier beginning not later than January 1, 2017. Accordingly, we proposed to add a new paragraph (c) to §414.1215 to indicate that the performance period is CY 2015 for value-based payment modifier adjustments made in the CY 2017 payment adjustment period. We solicited comment on this proposal.

The following is a summary of the comments we received.

<u>Comment</u>: Many commenters expressed the opinion that shortening the gap between the performance year and the adjustment year for the value-based payment modifier by 3

months does not represent a significant improvement. Commenters indicated that CMS should continue to seek ways to reduce the current 1-year gap between the close of the performance period and the beginning of the payment adjustment period. A number of commenters recommended that CMS adjust the performance period for quality data reported through PQRS and calculate the total per capita cost measures on an April 1 through March 31 basis, thus closing the gap by 3 months. Other commenters indicated that the increasing use of the new PQRS qualified clinical data registry reporting option can provide a window to reduce this gap considerably, a rolling 12-month cycle reported on a quarterly basis may be most effective for measurements with small sample populations, and a longer period of time may be required to show any improvement.

Response: A majority of the commenters did not support the option to adjust the performance period for quality data reported through PQRS and calculate the total per capita cost measures on an April 1 through March 31 basis and claimed that closing the gap by 3 months would not be a significant improvement. Also, there was not sufficient support among commenters for reporting PQRS data on a quarterly basis because it would be operationally difficult and burdensome on physicians. Therefore, we are finalizing a policy to use CY 2015 as the performance period for the value-based payment modifier adjustments that will apply during CY 2017. In the meantime, we will continue to consider options to close the gap between the performance period and the payment adjustment period and will continue to provide timely feedback to physician groups through the QRURs. One potential mechanism to close the gap would be to require quarterly reporting by eligible professionals or to truncate the time allowed for reporting after the performance period closes; however, we have not received comments from physicians and other clinicians supporting these approaches. Moreover, we believe it is critical

to calculate cost measures using a full 90 day claims runout so that measures accurately assess the cost of care. We encourage stakeholders to share their thoughts and ideas on options to close the gap without imposing an undue administrative burden and while still allowing for meaningful quality and costs measurement. In the meantime, we expect that groups of physicians will become even more proficient at the use of EHR technology and establish real-time feedback on quality measures so that they have relevant performance information that they can act on at the point of care.

e. Quality Measures

In the CY 2013 PFS final rule with comment period (77 FR 69315), we aligned our policies for the value-based payment modifier for CY 2015 with the PQRS reporting mechanisms available to groups of physicians in CY 2013, such that data that a group of physicians submitted for quality reporting purposes through any of the PORS group reporting mechanisms in CY 2013 would be used for calculating the quality composite under the qualitytiering approach for the value-based payment modifier for CY 2015. Moreover, all of the quality measures for which groups of physicians are eligible to report under the PQRS in CY 2013 are used to calculate the group of physicians' value-based payment modifier for CY 2015, to the extent the group of physicians submits data on such measures. We also established a policy to include three additional quality measures (outcome measures) for all groups of physicians subject to the value-based payment modifier: (1) a composite of rates of potentially preventable hospital admissions for heart failure, chronic obstructive pulmonary disease, and diabetes; (2) a composite rate of potentially preventable hospital admissions for dehydration, urinary tract infections, and bacterial pneumonia, and (3) rates of an all-cause hospital readmissions measure (77 FR 69315).

PORS Reporting Mechanisms: We noted in the proposed rule that we believe it is important to continue to align the value-based payment modifier for CY 2016 with the requirements of the PORS, because quality reporting is a necessary component of quality improvement. We also seek not to place an undue burden on physicians to report such data. Accordingly, for purposes of the value-based payment modifier for CY 2016, we proposed to include all of the PQRS GPRO reporting mechanisms available to group practices for the PQRS reporting periods in CY 2014 and all of the PORS reporting mechanisms available to individual eligible professionals for the PORS reporting periods in CY 2014. In addition, we proposed that groups of physicians with 25 or more eligible professionals would be able to elect to include the patient experience of care measures collected through the PQRS CAHPS survey for CY 2014 in their value-based payment modifier for CY 2016. These reporting mechanisms are described in Tables 24 through 27 of the CY 2014 PFS proposed rule (78 FR 43367-43370). We also proposed to update our regulations at §414.1220 to reflect this proposal. We noted in our proposal that the criteria for satisfactory reporting of data on PQRS quality measures for individual eligible professionals via qualified registries for the CY 2014 PQRS incentive and CY 2016 PQRS payment adjustment permits the use of a 6-month reporting period. We stated that we believed that data submitted via qualified registries for this 6-month reporting period would be sufficiently reliable on which to base a group of physicians' quality composite score under the value-based payment modifier because in order for us to use the data to calculate the score, we would require data for each quality measure on at least 20 beneficiaries, which is the reliability standard for the value-based payment modifier (77 FR 69322-69323). Given this level of reliability, we believe a 6-month reporting period would be sufficient for the purpose of evaluating the quality of care furnished by a group of physicians subject to the value-based

payment modifier. We solicited comment on this proposal. The following is a summary of the comments we received on this proposal.

Comment: The majority of commenters supported our proposal to permit groups practices and individual EPs to use all of the PQRS reporting mechanisms available to them in CY 2014 for the value-based payment modifier, including the use of the PQRS CAHPS survey. Commenters indicated that there should be a wide range of reporting options available in order to increase participation in the PQRS. Others commenters urged us to the retain the PQRS Administrative Claims reporting option that we have in place for CY 2013 and to include in Category 1 those groups of physicians that elect the Administrative Claims option.

Response: We appreciate the comments received in support of our proposal. As discussed previously, one of the principles governing our implementation of the value-based payment modifier is that physicians should be able to choose the level (individual or group) at which their quality performance will be assessed, reflecting physicians' choice over their practice configurations. We believe that the various PQRS reporting mechanisms – which include both individual and group reporting mechanisms allow physicians to choose how best to report quality information given their practice configuration. In response to the commenters' suggestion that we continue to use the PQRS Administrative Claims reporting option for the value-based payment modifier, we believe this option does not match our long-term goals to encourage reporting by physicians and groups of physicians of quality measures that best match their practices. In addition, our analysis of the CY 2012 QRURs shows that average reliability is substantially higher for the PQRS measures reported by physicians and groups of physicians than the reliability of many of the 14 Administrative Claims measures.

Accordingly, we are finalizing our proposal to include for the CY 2016 value-based payment modifier all of the PQRS GPRO reporting mechanisms available to group practices for the PQRS reporting periods in CY 2014 and all of the PQRS reporting mechanisms available to individual eligible professionals for the PQRS reporting periods in CY 2014. In addition, we are finalizing our proposal that groups of physicians with 25 or more eligible professionals would be able to elect to include the patient experience of care measures collected through the PQRS CAHPS survey for CY 2014 in their value-based payment modifier for CY 2016. We are finalizing the corresponding changes to § 414.1220 as proposed.

PQRS Quality Measures: We also proposed to use all of the quality measures that are available to be reported under these various PQRS reporting mechanisms, including quality measures reported through qualified clinical data registries, to calculate a group of physicians' value-based payment modifier in CY 2016 to the extent that a group of physicians submits data on these measures. We noted that the three outcome measures that we finalized in the CY 2013 PFS final rule with comment period and in §414.1230 – the two composites of rates of potentially preventable hospital admissions and the all-cause hospital readmission measure – would continue to be included in the quality measures used for the value-based payment modifier in CY 2016.

For those groups of physicians subject to the value-based payment modifier in CY 2016 whose eligible professionals participate in the PQRS as individuals rather than as a group practice under the GRPO (that is, groups of physicians that are assessed under the finalized 50 percent threshold), we proposed to calculate the group's performance rate for each measure reported by at least one eligible professional in the group of physicians by combining the weighted average of the performance rates of those eligible professionals reporting the measure.

We noted that if all of the eligible professionals in a group of physicians subject to the CY 2016 value-based payment modifier satisfactorily participate in a PQRS qualified clinical data registry in CY 2014 and we are unable to receive quality performance data for those eligible professionals, for purposes of the value-based payment modifier, we proposed to classify the group's quality composite score as "average" under the quality-tiering methodology, because we would not have data to reliably indicate whether the group should be classified as high or low quality under the quality-tiering methodology. We also proposed to add a new subsection to our regulations at §414.1270 to reflect our proposals about how to assess quality performance for groups assessed under the proposed 70 percent threshold ((which is being finalized as 50 percent, as discussed above). We solicited comment on these proposals.

The following is a summary of the comments we received regarding these proposals.

Comment: Most commenters supported use of all PQRS measures available to groups of physicians and individual physicians and eligible professionals for the CY 2014 PQRS reporting periods. The commenters appreciated "CMS' flexibility in allowing performance on all PQRS measures to be included in the value-based payment modifier." Several commenters expressed concern over the lack of measures in the PQRS measure set that are appropriate for certain specialties and urged that these specialties not be penalized under the value-based payment modifier solely based on the limited availability of quality measures for those specialties. One commenter, however, suggested that rather than straining Medicare's limited resources to implement dozens of process measures and shortening reporting times, we should use a small number of outcome measures (calculated at the population level within a specified geographic area) that are important to taxpayers and beneficiaries for the value-based payment modifier.

We did not receive comments on our proposal to calculate a group's performance rate for each measure reported by at least one eligible professional in the group of physicians by combining the weighted average of the performance rates of those eligible professionals reporting the measure. Despite the lack of comments on how we should calculate a group score when EPs in the group report PQRS quality measures as individuals, commenters cited our proposal to address the potential scenario of not receiving data from qualified clinical data registries as a "reasonable way" to tier groups whose EPs report using a PQRS qualified clinical data registry in CY 2014.

Response: We appreciate commenters' support for our proposals. We believe that the PQRS measure set is robust and, as described above, we have included new measures to address measure gaps (section III.H.9. above). In addition, we have collaborated with the specialty societies in order to increase the number of measures available specifically for specialists. We appreciate the suggestion to use a small number of outcome measures calculated at the population level, and we will continue to examine ways to add to the three outcome measures that we currently utilize for the value-based payment modifier as we continue our implementation of the value-based payment modifier.

We also note that we expect to receive data in a timely manner for EPs who report using qualified clinical data registries (see discussion above section III.H). For that reason, it is not absolutely necessary that we finalize our proposal to classify as "average" under the quality-tiering methodology a group of physicians subject to the CY 2016 value-based payment modifier that falls under Category 1 and whose individual EPs satisfactorily participate in a PQRS qualified clinical data registry in CY 2014. Nonetheless, out of an abundance of caution, we are

finalizing the proposal as a precaution to address the scenario where in fact we would be unable to receive data in a timely manner for a group's EPs.

Accordingly, we are finalizing our proposal to use all of the quality measures that are available to be reported under the various PQRS reporting mechanisms to calculate a group of physicians' CY 2016 value-based payment modifier to the extent that the group (or individual EPs in the group, in the case of the 50 percent threshold option) submits data on those measures. We also are finalizing our proposal for those groups of physicians availing themselves of the "50 percent threshold option" discussed above to calculate the group's performance rate for each measure reported by at least one eligible professional in the group of physicians by combining the weighted average of the performance rates of those eligible professionals reporting the measure. In addition, for those groups assessed under the "50 percent threshold option," we are finalizing our proposal to classify a group's quality composite score as "average" under the quality-tiering methodology, if all of the eligible professionals in the group satisfactorily participate in a PQRS qualified clinical data registry in CY 2014 and we are unable to receive quality performance data for those eligible professionals. We clarify that if some EPs in the group report data using a qualified clinical data registry and we are unable to obtain the data, but other EPs in the group report data using claims, registry, or EHR reporting mechanism, we would calculate the group's score based on the reported performance data that we obtain through claims, registries, or EHRs. We are finalizing our proposed addition to the regulations at §414.1270 without modification.

We noted that when the value-based payment modifier applies to all physicians and groups of physicians in CY 2017 based on performance during CY 2015, we anticipate continuing our policy to align with the PQRS group reporting for all groups of physicians of two

or more eligible professionals, and we anticipate permitting physicians who are solo practitioners to use any of the PQRS reporting mechanisms available to them under the PQRS for reporting periods in CY 2015 for purposes of the value-based payment modifier in CY 2017. Although we did not propose to adopt this policy, we solicited comment on this approach to align certain aspects of the CY 2017 value-based payment modifier with the quality measures and reporting mechanisms used in the PQRS.

Comment: Commenters supported the approach to align the CY 2017 value-based payment modifier with the PQRS quality measures and the available PQRS reporting mechanisms. The commenters recognize that with the PQRS they have a choice of measures that serve as the basis for assessment. They also believe that alignment between the PQRS and the value-based payment modifier helps to minimize administrative burden to physician practices. Commenters encouraged "CMS to continue in future rulemaking cycles to allow physicians the flexibility to choose measures that are applicable to their scope of practice."

Response: We appreciate the commenters' support for our overall approach to the CY 2017 value-based payment modifier. We anticipate making proposals in future rulemaking to apply the value-based payment modifier to all physicians and groups of physicians in 2017.

f. Inclusion of the Medicare Spending per Beneficiary Measure in the Value-Based Payment Modifier Cost Composite

In the CY 2014 PFS proposed rule, we summarized the five cost measures that we previously finalized for the value-based payment modifier cost composite and restated our previously expressed belief that the value-based payment modifier should incorporate additional measures that are consistent with the National Quality Strategy and other CMS quality initiatives. As a step toward that goal, beginning with the CY 2016 value-based payment

modifier, we proposed to expand the cost composite to include an additional measure, the Medicare Spending per Beneficiary (MSPB) measure (with one modification as discussed in the CY 2014 PFS proposed rule) (78 FR 43493 through 94). We proposed that the MSPB measure would be added to the total per capita costs for all attributed beneficiaries domain of the value-based payment modifier. We proposed that the MSPB measure would be equally weighted with the other cost measure in that domain - the total per capita cost measure. We stated that the rationale for our proposal to include the MSPB measure in the total per capita costs for all attributed beneficiaries domain, rather than the total per capita costs for all attributed beneficiaries with specific conditions domain, was that the MSPB measure is similar to the total per capita costs measure.

In addition, we stated our intent to propose, in future rulemaking, to replace the four measures in the total per capita costs for all attributed beneficiaries with specific conditions domain with cost measures derived from the CMS Episode Grouper and other episode-based costs. We solicited comments on these potential changes to the condition-specific cost measures as well as on the other elements of the cost composite in preparation for the CY 2015 performance period affecting payment adjustment year CY 2017.

In the proposed rule, we provided background on the MSPB measure, which we have already finalized for inclusion in the Hospital Inpatient Quality Reporting (IQR) and Value-Based Purchasing (VBP) Programs. We stated that, when viewed in light of other quality measures, as a part of the value-based payment modifier measure set, we believe that inclusion of the MSPB measure would enable us to align incentives and similarly recognize physician groups involved in the provision of high-quality care at a lower cost to Medicare.

<u>Construction of the MSPB measure</u>. In the CY 2014 PFS proposed rule, we summarized the construction of the MSPB measure used for the Hospital IOR and VBP Programs (78 FR 43494). We

stated that the measure includes all Medicare Part A and Part B payments during an MSPB episode spanning from 3 days prior to an index hospital admission through 30 days post discharge with certain exclusions. Costs for each episode are risk adjusted and the included payments are standardized to remove differences attributable to geographic payment adjustments and other payment factors. The payment standardization is the same methodology used for the existing total per capita cost measures included in the value-based payment modifier. We explained that, under the Hospital IQR and VBP Programs, the payment-standardized costs for all index admissions are summed and divided by the sum of the expected costs from the risk adjustment model. This ratio is then multiplied by the national average MSPB episode cost to give the hospital's MSPB amount. We then divide an individual hospital's MSPB amount by the national median MSPB amount to calculate a ratio, which we publicly report on Hospital Compare and use to generate a measure score for the Efficiency domain under the Hospital VBP Program. We referred readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51618 through 51627) for a detailed description of the MSPB measure used in the Hospital IOR and VBP Programs and noted that a detailed specification document (entitled "MSPB Measure Information Form") and the payment standardization methodology (entitled "CMS Price Standardization") can be found in the "Measure Methodology" section at

http://qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=12 28772053996.

We proposed a slightly revised calculation for inclusion of the MSPB measure in the value-based payment modifier. We proposed not to convert the MSPB amount to a ratio as is done to compute a hospital's MSPB measure under the Hospital IQR and VBP Programs, but rather to use the MSPB amount as the measure's performance rate. We solicited comment on our proposals to include the MSPB measure (as modified per the discussion above) in the value-based payment modifier cost composite and to add the measure to the total per capita costs for all attributed beneficiaries domain. We also proposed to revise the regulations at §414.1235 to include the Medicare Spending per Beneficiary measure in the set of cost measures for the value-based payment modifier and §414.1260(b)(1)(i) to include the Medicare

Spending per Beneficiary measure in the total per capita costs for all attributed beneficiaries domain. We received many comments on our proposal to include the MSPB measure as a part of the cost composite for the Physician Value-Based Payment Modifier beginning with the CY 2014 performance period and CY 2016 payment adjustment year.

Comment: Many commenters opposed our proposal to include the MSPB measure in the cost composite. While several of these acknowledged the importance of promoting efficiency for physicians and incentivizing coordination of care and reduction in delivery system fragmentation, they expressed reservations regarding implementation of the measure for the CY 2014 performance year and the CY 2016 value-based payment modifier. The reasons given for the lack of support for this measure's addition to the cost composite included: lack of experience with this measure as it applies to physicians and physician groups, with the suggestion that it first be piloted or included in PORS or Quality and Resources Use Reports (QRURs) before it is included in the value-based payment modifier; lack of NQF endorsement; perceived lack of physician control over care plan; concerns about actionability, that is, whether the information from the measure can be used by physician groups to improve performance; or perceived lack of measure specification or testing at the physician level. One commenter suggested that the measure first be piloted on populations with clearly inappropriate spending patterns. One commenter questioned the applicability of the measure to physician groups practicing in dedicated cancer centers, and two expressed that measure variation was not reflective of pathology services. One of these commenters suggested that the Hospital VBP Program total performance score for the hospital in which a pathologist practices should be used in the value-based payment modifier, rather than the MSPB measure rate.

Response: We agree with the commenters that coordination of care and reduction of delivery system fragmentation are important goals and inclusion of this measure in the value-based payment modifier is an important step toward incentivizing quality improvements. We also agree that it is important for physician groups to gain experience with the measure. Accordingly, we will begin including information on the MSPB measure (that is, performance rate, beneficiary information) in the QRURs that will be disseminated to all groups in 2014 based on 2013 performance (and going forward),

before it is included in the CY 2016 value-based payment modifier that will adjust physician groups' payments based on 2014 performance. We also note that during the first year the measure is included in the value-based payment modifier, groups of physicians with 10-99 eligible professionals in Category 1 will not receive any downward payment adjustments under the quality-tiering methodology. Because we are finalizing our proposal to "hold harmless" groups of physicians with 10-99 EPs in Category 1 from any downward payment adjustment in CY 2016, we believe this policy addresses commenters' concerns, because it means that these groups will have at least 2 years' experience with the measure before it could affect payments. We believe that piloting the measure is not necessary, because hospitals already are being assessed with this measure under the Hospital IQR and VBP Programs, and we seek to align incentives among hospitals and physicians as quickly as possible. We thank the same commenter for the suggestion to use the total performance score for the hospital in which a pathologist practices rather than the MSPB measure, and will take this proposal under consideration in future rulemaking. While groups of 100 or more eligible professionals could potentially receive a downward payment adjustment under the CY 2016 value-based payment modifier (based on their CY 2014 performance), those groups also will have received a QRUR of their measure performance in advance of the performance being used in the value-based payment modifier. We also note that all groups of 25 or more eligible professionals were able to obtain a QRUR based on CY 2012 performance that provided detailed information about the beneficiaries attributed to their groups. These 2012 reports provided details about the beneficiaries' hospitalizations, so that physician groups may begin to work with the hospitals that treat their attributed beneficiaries to improve care coordination, decrease fragmentation, and improve efficiency. We believe that these steps are sufficient to allow physician groups to gain experience with the MSPB measure and do not believe that it would be necessary to first implement the measure on some subset of physician groups that might be expected to have inappropriately high spending. We disagree that the measure is not adequately specified for application to physician groups. As we noted in the proposed rule (78 FR 43494), the measure's detailed specifications are available in the "Measure Information Form" located under the "Measure Methodology" section on Quality Net

(http://www.qualitynet.org/dcs/ContentServer?pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228 772053996).

We disagree with commenters' suggestion that physicians have little control over the care provided to beneficiaries who are hospitalized. As noted by some commenters on this proposed rule, as well as on the FY 2013 IPPS proposed rule, there is value in aligning incentives between hospitals and the physicians who practice in them. We acknowledge that physician groups may contribute to the MSPB episode cost to varying degrees. As discussed in more detail below, we are finalizing an attribution methodology that we believe addresses commenters' concerns regarding the degree to which a given physician group contributed to the costs for a given MSPB episode. By attributing episodes included in the MSPB measure only to the physician group that provided the plurality of Part B services during the hospital stay, we believe we are recognizing the group of physicians that is in a strong position to improve coordination, decrease fragmentation, and control Medicare expenditures. In addition, the physician group that provided the plurality of Part B services during the stay is in a strong position to coordinate care with the hospital, addressing commenter concerns about measure actionability discussed above. While we appreciate the value of NOF endorsement, we note that it is not required for inclusion of a measure in the value-based payment modifier. We intend to submit the physician version of the MSPB measure through a future endorsement project; however, at this time, we have proposed a measure that is substantially similar to that currently undergoing the NQF endorsement process, which is a measure used to assess spending for hospitals, rather than physician groups. We believe that inclusion of the MSPB measure in the value-based payment modifier will help to align incentives and promote coordination of care and improved efficiency across provider types, including hospitals and the physician groups who practice in them.

We do not believe it would be appropriate to exclude any physician specialty from inclusion in the measure, as such an exclusion could undermine the effort to incentivize care coordination. We also note that the MSPB measure is built around index admissions at IPPS hospitals, not PPS-exempt cancer hospitals.

Comment: Several commenters expressed their support for inclusion of the MSPB measure in the cost composite. The reasons these commenters provided for their support included: the belief that a robust cost measure set will further transform the Medicare payment system to a system that rewards efficient, effective care and helps address the critical issue of health care; valuing consistency with the use of this measure in the Hospital VBP Program; and the belief that inclusion of this measure could incentivize team-based care among hospitals and their physicians, including improved discharge planning better discharge instructions and education. One commenter also noted that measurement using the MSPB measure enables providers to develop their own care delivery processes in order to improve performance on the measure. One commenter supported the inclusion of the MSPB measure while suggesting that CMS also continue to explore how cost measures for specific conditions or treatments might be used to further expand the cost composite.

Response: We thank the commenters for their support of our proposal to include the MSPB measure in the cost composite for the value-based payment modifier. We agree that this measure's inclusion will contribute to the continued development of a more robust cost measure set for the value-based payment modifier and that it will incent improved care coordination among physicians and hospitals, improved efficiency, and control of health care costs, and it will help to align incentives across our incentive payment programs. We agree that continuing to expand the cost composite measure set would benefit the value-based payment modifier, and we will consider including specific episode cost measures through future rulemaking.

Comment: We received several comments related to the construction of the MSPB measure itself. One commenter expressed concern with the measure's inability to assess physician groups and their ability to avoid hospitalization for their patients, while several suggested that the risk adjustment methodology should go further to address factors including: socioeconomic status, dual eligibility for Medicare and Medicaid, a frailty factor, functional status, sub-specialty of the physician; place of service; or CPT codes, rather than Major Diagnostic Categories (MDCs). A few commenters expressed concern that a lack of specialty mix could penalize physician practices that focus on home health, skilled nursing

facility care, or rehabilitation. A few commenters stated that a measure of provider-level care would be more reliable than one of facility-level or mixed facility- and provider-level care. A few commenters also expressed concern that the measure does not include Part D data. Finally, a few commenters expressed concern that the fact that the MSPB measure does not reflect other aspects of care quality could lead to the unintended consequence of reduced access to or provision of needed care or avoidance of complex patients. One of these commenters suggested that MSPB should therefore not be weighted more heavily than patient experience or outcome measures.

Response: We appreciate the commenters' consideration of the MSPB measure, and we will continue to consider ongoing refinements to it, as we gain experience with the measure. We proposed to use the MSPB amount as the measure rate under the physician value-based payment modifier, rather than converting it to a ratio as we do under the Hospital IQR and VBP Programs. For each cost measure finalized for use in the physician value-based payment modifier, including the MSPB amount, we also are finalizing use of a specialty adjustment that allows for peer group comparisons while factoring in specialty mix (see section III.K.4.g.2. below). The specialty adjustments are made to risk-adjusted dollar amounts, rather than to ratios such as those used under the Hospital IQR and VBP programs. Aside from that proposed difference in expression of the measure rate, we believe that it is important to maintain the measure's construction as closely as possible to that used under the Hospital VBP and IQR Programs, in the interest of alignment across programs and to provide consistent information to both hospitals and their physicians so that they are assessed against the same yardstick. We disagree that inclusion of this measure would incentive physicians to reduce provision of needed care to the beneficiaries they serve and avoid hospitalizations. As we stated in the FY 2013 IPPS/LTCH Final Rule (77 FR 53586), we do not believe that the Medicare Spending per Beneficiary measure itself should assess both cost and quality. We believe that a distinct measure of cost, independent of quality,

enables us to identify providers involved in the provision of high quality care at a lower cost to Medicare. Because the MSPB measure would be only one of six measures included in the valuebased payment modifier's cost composite, we believe that physicians' consideration for their patients' well-being as well as their performance on the other measures used for the value-based payment modifier would outweigh any potential incentive to reduce needed care to Medicare beneficiaries. We therefore believe that a cost composite weight that is equal to the quality composite weight provides a balance between incentives for physician groups to improve quality and to control cost. We will monitor for changes in utilization patterns. We disagree that the costs of care provided in the facility should be separated from those provided post-discharge. This would be counter to the goal of incentivizing coordination between hospitals and physician group to ensure that Medicare beneficiaries receive effective, efficient care during and after hospitalization. We refer the reader to section III.K.4.g.2., Cost Composite Benchmarking and Peer Groups, for a discussion of the specialty adjustment for the MSPB measure, which addresses the commenter suggestion about specialty adjustment. That adjustment is made outside the construction of the MSPB measure itself and will be performed after the measure is calculated for a group of physicians. We do not believe that payments included in the MSPB measure should be adjusted for differences in site of service, as these differences reflect actual costs to the Medicare program. The payments included in the measure are adjusted according to the CMS Price Standardization methodology located at http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQne tTier4&cid=1228772057350, and they are standardized to remove differences attributable to geographic payment adjustments and other payment factors. Because many Medicare fee-for-

service beneficiaries obtain outpatient prescription drug coverage outside of Medicare Part D.

including Part D data in the MSPB measure would incorrectly indicate higher costs for these beneficiaries compared to others. We are considering possible approaches to payment-standardizing and operationalizing Part D costs. Regarding the comments related to the MSPB's risk adjustment methodology, we addressed similar comments in the IPPS/LTCH Final Rule and refer readers to that discussion (77 FR 53586 through 53588).

We did not receive any comments on our proposed regulation text changes at §414.1235 or §414.1260(b)(1)(i) and are, therefore, finalizing the proposed changes without modification.

Attribution of the MSPB measure to physician groups. In the CY 2014 PFS proposed rule, we proposed to attribute an MSPB episode to a group of physicians subject to the value-based payment modifier (as identified by a single TIN), when any eligible professional in the group submits a Part B Medicare claim under the group's TIN for a service rendered during an inpatient hospitalization that is an index admission for the MSPB measure during the performance period for the applicable calendar year payment adjustment period. Thus, the same index admission and MSPB episode could be attributed to more than one group of physicians.

We stated that attribution of the MSPB episode to all groups of physicians from which an eligible professional submits a Part B claim for a service rendered during the hospitalization is the best way to assign responsibility for, and encourage greater coordination of, care furnished to Medicare beneficiaries who are hospitalized. We stated that, based on CY 2011 claims data, the proposed approach would enable approximately 11,419 groups of physicians with at least 10 eligible professionals to have an MSPB measure score included in their cost composite (78 FR 43494). We noted that many of these groups would otherwise not receive a cost composite score, because they do not provide the requisite primary care services of the five annual total per capita cost measures and, therefore, are not attributed beneficiaries. We stated that our proposed

approach incentivizes hospitals and physicians to furnish efficient, effective care during a hospitalization and to coordinate post-discharge care to avoid unnecessary services and preventable readmissions. Further, we believe that this attribution approach fosters shared accountability between hospitals and physicians for the care they furnish to Medicare beneficiaries who are hospitalized. We proposed to add a new paragraph (b) to §414.1240 to indicate that a MSPB episode would be attributed to a group of physicians subject to the value-based payment modifier if any eligible professional in the group submits a Part B Medicare claim under the group's TIN for a service rendered during an inpatient hospitalization that is an index admission for the MSPB measure during the performance period for the applicable calendar year payment adjustment period. Groups of physicians would have a Medicare Spending per Beneficiary measure score included in their cost composite based on the proposed attribution methodology for the MSPB.

In the CY 2014 PFS proposed rule, we also sought comment on the alternative MSPB measure attribution approaches. We considered attributing an MSPB episode to a physician group when any eligible professional in the group billed a Part B claim for a service rendered at any time during the Medicare Spending per Beneficiary episode (that is, from 3 days prior to an index admission through 30 days post-discharge). We stated that this attribution approach would place an even stronger emphasis on shared accountability for care provided to Medicare beneficiaries who are hospitalized, both during and after their hospitalization. Based on 2011 claims data, we estimate that this attribution approach would enable an additional 3,017 groups of physicians with 10 or more eligible professionals to receive an MSPB measure performance rate for inclusion in the cost composite, as compared to our proposed attribution approach which considers only those eligible professionals who bill a Part B claim during the index admission.

As with our proposed approach, the same index admission and MSPB episode could be attributed to more than one group of physicians under this alternative approach. We welcomed public comment on the alternative attribution approach under which we would attribute an MSPB episode to a physician group if any eligible professional in the group billed a Part B service during the 3 days prior to an index admission through 30 days post hospital discharge.

We also considered two alternative methods which would attribute each MSPB episode to a single physician group. The MSPB episode could be attributed solely to the group of physicians that provided the plurality of Part B services either: (1) during the entire MSPB episode (that is, from three days prior to an index admission through 30 days post discharge); or (2) during the index admission only. We wish to clarify the explanation of "plurality" of services that we provided in the proposed rule. By "plurality," of services, we mean the highest total Medicare allowed amount for Part B services billed by any group of physicians who provided Part B services during a given portion of an MSPB episode (either the full episode or the index admission only). The group of physicians need not have billed the majority of the charges allowed by Medicare for Part B services furnished during a given portion of an episode, but rather the group's total allowed charges must be greater than any other group of physicians for that portion of the episode. These methods are single attribution approaches, unlike our proposal which is a multi-attribution approach.

Using 2011 claims, we analyzed the number of TINs, comprised of 10 or more eligible professionals, that would be attributed an MSPB measure rate under these alternative attribution methods given a minimum of 20 MSPB episodes required. Our analyses revealed that 7,799 TINs (out of approximately 17,000 TINs) would be eligible to receive an MSPB measure rate, if MSPB episodes were attributed to the group of physicians that provided the plurality of

Medicare Part B services during the entire MSPB episode. This represents a 46 percent decrease in the number of TINs that would receive an MSPB measure rate, were it attributed to a group from which an eligible professional rendered any Part B service during the entire episode. Our analysis also showed that 7,582 TINs would be eligible to receive an MSPB measure rate, if MSPB episodes were attributed to the physician group that billed the plurality of Medicare Part B payments during the index admission. This represents a 34 percent decrease in the TINs that would receive an MSPB measure rate, were it attributed to a group from which an eligible professional rendered any Part B service during the index admission.

In the proposed rule, we explained that we considered these two single attribution methods because they represent methods to identify groups of physicians that were "most responsible" for the Part B Medicare payments made during the episode. We did not propose these methods, because we believed our proposed multiple attribution approach better incentivizes a team approach to accountability for Medicare beneficiaries' care during a hospitalization. We stated our belief that our proposed attribution approach is further supported by the higher number of TINs that will be able to receive an MSPB measure rate under that methodology. We solicited comment, however, on these two alternative single attribution approaches we considered: Attributing an MSPB episode to the group of physicians that provided the plurality of Part B services billed either during the entire MSPB episode or during the index admission only.

In the proposed rule, we also explained two versions of a "hybrid" attribution method we considered. This methodology would attribute MSPB episodes to all TINs from which an eligible professional provided services representing at least 35 percent of the total Medicare Part B payments made either: (1) during the entire MSPB episode (that is, from three days prior to an

index admission through 30 days post discharge); or (2) during the index admission only. This alternative could result in multiple attribution, if two eligible professionals from different TINs each provided services representing at least 35 percent of the Part B Medicare payments during one of the episode portions described above (either the full episode or during the index admission only). The rationale for this attribution approach is that it ensures that the MSPB measure would be attributed to a group of physicians who had responsibility for a significant portion of the Medicare beneficiary's care during a given portion of the MSPB episode. We did not propose this alternative, because we believed that our proposed attribution approach better incentivizes a team approach to accountability for Medicare beneficiaries' care during and after a hospitalization. We welcomed public comment on this alternative attribution approach based on provision of services representing at least 35 percent of Medicare Part B payments made either during the entire MSPB episode or during the index admission only.

The following is a summary of the comments we received regarding the proposed attribution method and alternative methods.

Comment: One commenter tentatively supported our proposal to attribute MSPB episodes to any physician group from which an eligible professional billed a Part B service during an index admission for the MSPB measure. A few commenters stated that they would prefer either single attribution based on the plurality of Part B services during the hospital stay or attribution based on the "hybrid" approach of attributing to any group from which an eligible professional provided at least 35 percent of the Part B services billed during the hospital stay. One commenter supported attribution based either on plurality of Part B services provided during the hospital stay or on a hybrid attribution during either the hospital stay or the entire episode. The majority of commenters stated that they would prefer attribution to a single physician group

that provided the plurality of Part B services during the hospital stay. The commenters expressed their belief that our proposed attribution to any physician group from which an eligible professional billed a Part B claim during the index admission or episode was too broad, stating that it would not recognize physician groups' varying degrees of involvement in the patient's care during the episode, that it would not incentivize coordination of care, that the physician group to which the episode is attributed should have a minimum level of association with the patient's care, and that further analysis was needed before adopting such a broad attribution approach. One commenter expressed concern that attribution could inadvertently penalize inpatient physicians (for example, hospitalists) for costs beyond their control such as those occurring in the post-acute and outpatient settings or those incurred by specialists due to inadequate primary care. One commenter asked that we ensure that calculations used to specifically allocate costs associated with physician care versus care provided for the same patient in other settings or by other physicians/specialists are calculated and attributed accurately. One commenter stated that the measure could routinely penalize physicians whose practices focus on care settings such as nursing home or home care. One commenter stated that attribution should not be based on plurality of E&M services, and one commenter asked for clarification on how the measure would be attributed to groups that span a state or multiple regional hospitals.

Response: After considering the comments we received, we have decided not to finalize the attribution methodology that we proposed and instead will finalize the alternative, single attribution methodology that we considered, wherein an MSPB episode is attributed to the physician group (as identified by the Tax Identification Number) that furnished the plurality of Part B services during the index admission. This approach was the one most favored by

commenters. This approach recognizes physician groups' varying degrees of involvement in the patient's care during the episode, incentivizes coordination of care, and helps ensure that the physician group to which the episode is attributed has a minimum level of association with the patient's care. We are finalizing this policy in appreciation of the commenters' concern that the group to which an episode is attributed should have been involved in a significant portion of the beneficiary's care. The hospital and the physician group providing the plurality of care during the hospitalization will be best able to coordinate care and discharge and reduce fragmentation and unnecessary service provision. We believe this approach addresses commenters' concerns that a specialist might be attributed an episode for which they were not primarily responsible. We also prefer this attribution approach to one in which there is a set minimum level of involvement (such as the "hybrid" 35 percent approach we considered), because such an alternative attribution approach could result in some episodes not being attributed to any physician group, because the groups with the plurality of care did not reach the minimum percentage of care (for example, 30 percent). We believe that omitting such episodes from the measure would be counter to our interest in incentivizing a team approach to care provision for the beneficiaries with the most complicated cases.

We do not intend to attribute portions of an MSPB episode to different physician groups depending on the setting in which the care was provided, as suggested by one commenter. The MSPB measure is not constructed in that manner. Rather, it is attributed to an entity that is responsible for provision of a significant portion of the beneficiary's care and is capable of improving the efficiency of care throughout the episode. We do not believe the plurality of care during the stay approach to attribution will have a disproportionately adverse effect on those physician groups involved primarily in provision of home health or skilled nursing facility care,

because the physician whose group is attributed the episode must have provided more in-hospital care than any other physician. We wish to clarify that attribution of the MSPB measure would not be based on plurality of E&M services, but on plurality of all Part B services furnished during the index admission. In the case of a large physician group spanning multiple regions, the same policy would apply and the episode would be attributed to the TIN that billed the plurality of Part B services during the index admission. We appreciate the commenters' request for additional analysis of the effect of the attribution options we considered. As described in the proposed rule, we discussed the differences in the number of TINs that would receive an MSPB measure rate using a single attribution methodology based on plurality of care during the index admission, as compared to the number of TINs that would receive an MSPB measure rate under our proposed multiple attribution approach. We conducted additional analyses on the application of a minimum percentage of Medicare allowed charges that a physician group must have billed in order to be attributed an episode. As compared to a single attribution based on plurality with no minimum percentage, a multiple attribution approach requiring a group to have billed at least 35 percent of Medicare allowed charges resulted in a decrease from 7,582 attributed TINs to 7,389 attributed TINs, a decrease of 2.5 percent. This reduction is minimal, because while the floor precludes attribution of some episodes, multiple attribution allows some episodes to be attributed to more than one TIN. We found minimal difference in the number of TINs receiving an MSPB measure rate under the single attribution based on plurality and the multiple attribution based on a minimum 35 percent of charges approaches. Since imposing a minimum floor such as 35 percent of charges would lead to having un-attributed MSPB episodes that are not supported by these findings, we are finalizing the attribution approach recommended by the majority of commenters - a single attribution based on plurality of Part B services during the

hospital stay with no floor. As stated previously, we believe that attributing the MSPB episode to the physician group that provided the plurality of care during the hospitalization is the best approach to recognizing the group of physicians in the best position to affect improved coordination, decrease fragmentation, and control Medicare expenditures. We will monitor and examine the effects of this attribution approach as we implement the MSPB measure and may consider changes to this policy through future rulemaking.

Reliability standard for the Medicare Spending per Beneficiary measure for the valuebased payment modifier. We proposed that a group of physicians would have to be attributed a minimum of 20 MSPB episodes during the performance period to have their performance on this measure included in the value-based payment modifier cost composite. Table 86 shows the MSPB measure's reliability at various minimum numbers of episodes for all Medicare-enrolled TINs with at least one EP (not just TINs of 10 or more eligible professionals) from May 2011 through December 2011. (We note that Table 86 does not consider the specialty adjustment that we are finalizing in section III.K.4.g.2. below.) In this context, reliability is defined as the extent to which variation in the measure's performance rate is due to variation in the cost of services furnished by groups of physicians rather than random variation due to the sample of cases observed. Potential reliability values (known in statistics as the correlation coefficient) range from zero to one, where one (highest possible reliability) signifies that all variation in the measure's rates is the result of variation in the difference in performance across groups of physicians and is not due to random variation. Generally, reliabilities in the 0.40-0.70 range are often considered moderate and values greater than 0.70 high.

TABLE 86: Reliability of Medicare Spending per Beneficiary Measure for all TINs with at Least One Eligible Professional (May 2011- December 2011)

MSPB Episodes Attributed	Number of TINs	Percent of TINs	Mean risk-adjusted standardized cost per MSPB episode	Average Reliability
1-9	59,419	47%	\$20,493	0.65
10-19	12,332	10%	\$21,260	0.79
20-29	7,774	6%	\$21,225	0.83
30-39	5,839	5%	\$21,340	0.85
40-49	4,511	4%	\$21,324	0.87
50-99	12,648	10%	\$21,353	0.89
100-124	3,702	3%	\$21,403	0.91
125-149	2,761	2%	\$21,342	0.92
150-174	2,134	2%	\$21,316	0.93
175-199	1,673	1%	\$21,119	0.93
200+	14,933	12%	\$20,562	0.96

We also considered a minimum number of 10 episodes. The advantage of this lower minimum number is that it would enable us to calculate the MSPB measure for an additional 12,332 physician groups once we apply the value-based payment modifier to all physicians and groups of physicians. With a minimum of 10 cases, the measure is still very reliable, as illustrated in the Table 86. We proposed the minimum of 20 cases for initial implementation of this measure in the cost composite beginning with the CY 2016 value-based payment modifier because it strikes a balance between maintaining high reliability and including a large number of physician groups. We noted that this reliability standard we proposed is the same one we adopted in the CY 2013 PFS final rule with comment period that applies to quality and cost measures used in the value-based payment modifier (77 FR 69323). We welcomed public comment on our proposed minimum of 20 episodes for inclusion of the Medicare Spending per Beneficiary measure in the cost composite for the value-based payment modifier and on the alternative 10 episode minimum that we considered.

Comment: We received several comments on our proposed 20 episode minimum and the alternative 10 episode minimum we considered. Several commenters supported a minimum of 10 cases, in order to enable more groups to receive an MSPB measure performance rate for inclusion in the cost composite. These commenters noted that the MSPB measure is still very reliable at 0.70 with a minimum of 10 cases. Several commenters also stated that the proposed minimum of 20 cases was appropriate. One commenter suggested a minimum of 30 cases would be appropriate.

Response: We agree that the MSPB measure is still very reliable with a minimum of 10 cases, and we recognize that increasing the cost composite measure set for physician groups is a positive outcome of reducing the case minimum from our proposed minimum of 20. We believe that, because the measure is new, and a minimum of 20 cases still allows a substantial number of physician groups to have an MSPB measure rate in their cost composites, the proposed minimum of 20 cases is most appropriate for this measure's initial inclusion in the value-based payment modifier. We believe that a minimum of 20 cases strikes a good balance between preserving high reliability and maximizing the number of physician groups that receive an MSPB measure rate as part of their cost composite. After consideration of all public comments on the inclusion of the MSPB measure in the cost composite for the CY 2016 physician value-based payment modifier, we are finalizing the following policies:

We proposed a slightly revised calculation for inclusion of the MSPB measure in the value-based payment modifier. We proposed not to convert the MSPB amount to a ratio as is done to compute a hospital's MSPB measure under the Hospital IQR and VBP Programs, but rather to use the MSPB amount as the measure's performance rate.

We are finalizing inclusion of the MSPB measure as proposed in the cost composite beginning with the CY 2016 value-based payment modifier, with a CY 2014 performance period. As we proposed, we will use the MSPB amount as the measure's performance rate rather than converting it to a ratio as is done under the Hospital IQR and VBP Programs.

We are finalizing that the MSPB measure will be added to the total per capita costs for all attributed beneficiaries domain and equally weighted with the total per capita cost measure. It will not be added to the total per capita costs for all attributed beneficiaries with specific conditions domain.

We are finalizing the method under which an MSPB episode will be attributed to a single group of physicians that provides the plurality of Part B services during the index admission, for the purpose of calculating that group's MSPB measure rate.

We are finalizing a minimum of 20 MSPB episodes for inclusion of the MSPB measure in a physician group's cost composite.

We are finalizing regulation text as proposed at §414.1235 and §414.1260(b)(1)(i).

We are finalizing the regulation text at §414.1240(b) to read: For the MSPB measure, an MSPB episode is attributed to the group of physicians subject to the value-based payment modifier whose eligible professionals submitted the plurality of claims (as measured by allowable charges) under the group's TIN for Medicare Part B services, rendered during an inpatient hospitalization that is an index admission for the MSPB measure during the applicable performance period described at §414.1215.

- g. Refinements to the Cost Measure Composite Methodology
- (1) Average Cost Designations in Certain Circumstances

In the CY 2013 PFS final rule with comment period (77 FR 69322), we established a policy to create a cost composite for each group of physicians subject to the value-based payment modifier that includes five payment-standardized and risk-adjusted annual per capita cost measures. To calculate each group's per capita cost measures, we first attribute beneficiaries to the group of physicians. We attribute beneficiaries using a two-step attribution methodology that is used for the Medicare Shared Savings Program and the PQRS GPRO and that focuses on the delivery of primary care services (77 FR 69320). We have observed that groups of physicians that do not provide primary care services are not attributed beneficiaries or are attributed fewer than 20 beneficiaries and, thus, we are unable to calculate reliable cost measures for those groups of physicians (77 FR 69323). Given this development, we proposed that, to the extent that we are unable to attribute a sufficient number of beneficiaries to a group of physicians subject to the value-based payment modifier and thus are unable to calculate any of the cost measures with at least 20 cases, the group of physicians' cost composite score would be classified as "average" under the quality-tiering methodology. We believe this policy is reasonable because we would have insufficient information on which to classify the group of physicians' costs as "high" or "low" under the quality-tiering methodology. Moreover, we believe that to the extent a group of physicians' quality composite is classified as "high" or "low," the groups of physicians' value-based payment modifier should reflect that classification. Accordingly, we proposed to add a new paragraph at §414.1270 to reflect this proposal that groups of physicians in Category 1 for which we attribute fewer than 20 cases to calculate any cost measure would have their cost composite classified as "average" cost. We solicited comment on this proposal. The following is summary of the comments we received regarding this proposal.

Comment: The majority of comments received on this proposal were from commenters who supported our proposal and agreed that this was a reasonable proposal because CMS would have insufficient information to classify the group's cost as high or low, and other assumptions would be unfair to practices attributed fewer than 20 beneficiaries. The few commenters who opposed the proposal believed that it would unfairly advantage physician groups that have unnecessarily high costs and disadvantage providers who provided exceptional care at very low costs. One of the two commenters who opposed this proposal suggested that CMS could remove costs from the value-based payment modifier determination for such groups.

Response: We continue to believe that groups that are attributed fewer than the minimum case size of 20 beneficiaries would not allow for the calculation of reliable cost measures. We are concerned that not classifying the group as average when it has fewer than 20 attributed beneficiaries would increase the likelihood that its cost measures could fluctuate greatly from year to year, so we disagree with some of the commenters who stated that it would unfairly advantage or disadvantage different physician groups.

After consideration of the comments received, we are finalizing our proposal and adding a new paragraph at §414.1270 to reflect the proposal that groups of physicians in Category 1 for which we attribute fewer than 20 cases to calculate any cost measure have their cost composite classified as "average" cost.

Comment: Some commenters expressed or reiterated previously stated concerns about CMS' use of total per capita cost measures for the value-based payment modifier. In the CY 2012 PFS final rule with comment period (76 FR 73434), we finalized the use of total per capita cost measures and per capita cost measures for beneficiaries with four chronic conditions (chronic obstructive pulmonary disease, coronary artery disease, diabetes, and heart failure) in

the value-based payment modifier. In the CY 2013 PFS final rule with comment period (77 FR 69318), we finalized the use of the CMS Hierarchical Condition Category (HCC) model to risk adjust these total per capita cost measures in the value-based payment modifier. Arguments against the total per capita cost measures that commenters raised in response to the CY 2014 PFS proposed rule included that the cost measures reflect the total amount billed per patient by Medicare overall rather than the amount billed per patient by just the medical group, may not be appropriate for some specialists, and was not developed for nor tested in physician practices. Some commenters expressed concerns that the risk adjustment used in the total per capita cost measures is inadequate, either because of concerns about the CMS Hierarchical Condition Category (HCC) model or because the risk adjustment method lacked adjusters for physicians that tend to treat non-compliant patients. One commenter requested that CMS ensure that the expenditures are adjusted for geographic differences in input costs.

Other concerns raised by commenters included the potential for groups to shift drug costs from Part B to Part D, since Part D is not included in the cost measure. Several other commenters requested that CMS not use total per capita cost measures in the value-based modifier until we have developed and tested more focused episode-based cost measures. One commenter expressed concern about potential problems in shifting from the ICD-9-CM to the ICD-10-CM system, since the HCC model assigns prior year ICD-9-CM diagnosis codes to 70 high cost clinical conditions.

Response: We continue to believe that the total per capita cost measures provide useful information and are appropriate to incent physician groups who are in a good position to oversee annual costs to do so. We refer readers to previous CMS responses to a number of concerns raised again this year (about, for example, the appropriateness of the total per capita cost

measure for some specialists and the adequacy of the risk adjustment used for the measure) that were discussed in the CY 2012 (76 FR 73433 through 73436) and CY 2013 PFS final rules (77 FR 69315 through 69318). We also reiterate that the total per capita cost measures are payment-standardized (77 FR 69316 through 69317), which removes regional or local price differences that may lead to cost variation that a physician group cannot influence. We are aware of the commenters' concerns with total per capita cost measures and the risk adjustment approach, and we will monitor the situation as we implement the value-based payment modifier. If warranted, we will propose modifications to the total per capita cost measures and the risk adjustment approach in future rulemaking.

Regarding the potential to shift drug costs from Part B to Part D, we will take this comment into consideration as we monitor the impacts when the value-based payment modifier is implemented. Regarding testing episode-based cost measures, we have not yet proposed using output from the CMS episode grouper – that is currently under development and discussed in the Physician Feedback Program section (see section III.K.5.c.) – in the value-based payment modifier. We will consider proposing to include episode-based cost measures in future years' value-based payment modifiers (beyond 2016) through future rulemaking after we have thoroughly tested the CMS episode grouper and groups have seen their performance on them. We believe, however, that total per capita cost is a useful measure of total volume of healthcare services to Medicare beneficiaries and encourages shared accountability for beneficiary care and we have shared the results of this measure with all groups of 25 or more eligible professionals. Therefore, we disagree with the commenters who are calling for a delay in the use of the total per capita cost measure in the value-based payment modifier. Finally, we are studying the impacts of the planned ICD-9 to ICD-10 conversion across the Medicare program.

Comment: Some commenters expressed concerns about CMS using cost measures that have not been endorsed by the National Quality Forum (NQF), while others stated agreement with some of the concerns about the total per capita cost measure that were raised by the NQF Cost and Resource Use Committee (for example, concerns about the total per capita cost measure's reliability, validity, and usability, as well as lack of inclusion of Part D costs in the measure). One commenter expressed appreciation to CMS for taking a thoughtful approach to the implementation of the cost measures (via NQF submission).

Response: We submitted the total per capita cost measure for NQF endorsement in January 2013. (For further information, please see materials related to the submission of NQF candidate measure #2165 (Payment-Standardized Total Per Capita Cost Measure for Medicare Fee-for-Service (FFS) Beneficiaries) in the Cost and Resource Use 2012: Phase 1 section of the NQF website – http://www.qualityforum.org/Projects/c-d/Cost and Resource 2012 Phases 1 and 2/Cost and Resource Use 2012 Phase 1.aspx#t =2&s=&p=5%7C.) In the final voting in September 2013, the NQF Cost and Resource Use Committee narrowly voted against the measure by a count of 12 in support and 13 in opposition. We anticipate addressing the Committee's concerns in future rulemaking, especially regarding our attribution model and how best to incorporate socioeconomic status in our measure, after the NQF provides additional guidance regarding risk adjustment for resource use measures.

Consistent with the policy we established in the CY 2013 PFS final rule, we will continue to use the total per capita cost measures in the value-based payment modifier, and we will continue to evaluate the measure methodology and update the measure as appropriate.

(2) Cost Composite Benchmarking and Peer Groups

Once we calculate the cost measures for each group of physicians subject to the value-based payment modifier, we create the cost composite by calculating a standardized score for each cost measure and then placing the measures into one of two equally weighted domains: (1) the total per capita costs for all attributed beneficiaries domain; and (2) the total per capita costs for attributed beneficiaries with specific conditions domain. This standardized score is referred to in statistical terms as a Z-score. To arrive at the standardized score for each cost measure, we compare the performance for each group's cost measures to the benchmark (national mean) of other groups subject to the value-based payment modifier (peer group) for the same performance year. Specifically, we calculate the benchmark for each cost measure as the national mean of the performance rates among all groups of physicians to which beneficiaries are attributed and that are subject to the value-based payment modifier.

Using 2011 claims data, we examined the distribution of the overall total per capita cost measure among all groups of physicians with one or more eligible professionals to determine whether comparisons at the group level would be appropriate once we apply the value-based payment modifier to smaller groups of physicians and solo practitioners. We found that our current peer grouping methodology could have varied impacts on groups of physicians that are comprised of different physician specialties. This result occurs because the peer group for the per capita cost benchmarks is based on a national mean calculated among all groups of physicians subject to the value modifier rather than determined more narrowly (for example, within a physician specialty).

To address this issue beginning with the CY 2016 value-based payment modifier, we considered two methods that account for the group practice's specialty composition so that our quality-tiering methodology produces fair peer group comparisons and, ultimately, correctly

ranks group of physicians based on actual performance. Taking account of physician specialties in making cost comparisons is similar to the approach we have used in the CY 2010 and CY 2011 Quality and Resource Use Reports (QRURs) for individual physicians in which we made cost comparisons at the individual physician specialty level.

The first method, "specialty adjustment," accounts for the specialty composition of the group prior to computing the standardized score for each cost measure. This method enables us to develop comparable benchmarks for the risk-adjusted cost measures against which to evaluate groups of physicians of smaller size who often have fewer or single specialty composition.

More specifically, this method adjusts the standardized score methodology to account for a group's specialty composition using three steps:

Step 1: Create a specialty-specific expected cost based on the national average for each cost measure (referred to as the "national specialty-specific expected costs"). To do so, we attribute beneficiaries to a group using the plurality of primary care services methodology that we finalized in the CY 2013 PFS final rule with comment period (77 FR 69316). For each specialty, we calculate the average cost of beneficiaries attributed to groups of physicians with that specialty, weighted by the number of EPs in each group.

Step 2: Calculate the "specialty-adjusted expected cost" for each group of physicians by weighting the national specialty-specific expected costs by the group's specialty composition of Part B payments. That is, the specialty-adjusted expected cost for each group is the weighted average of the national specialty-specific expected cost of all the specialties in the group, where the weights are each specialty's proportion of the group's Part B payments. The Part B payments for each specialty are determined based on the payments to each EP in the group, and each EP is identified with one specialty based on its claims.

Step 3: Divide the total per capita cost by the specialty-adjusted expected cost, and multiply this ratio by the national average per capita cost so that we can convert this ratio to a dollar amount (referred to as the "specialty-adjusted total per capita cost") that can then be used in the standardized (Z-) score to determine whether a group can be classified as high cost, low cost, or average.

Below, we illustrate the three steps of the specialty adjustment to the standardized score with an example. Assume for simplicity that only two TINs and two specialties exist: TIN 1 and TIN 2, and Specialty A and Specialty B. For this example, assume that the total per capita costs and specialty shares are as shown in Table 87.

TABLE 87: Example of Calculating Specialty-Adjusted Total Per Capita Cost: Assumptions

	Risk- Adjusted Per Capita	Number of Attributed	Number of EPs in TIN by Specialty Type	Specialty Share	Specialty Share of Part B Payments in
TIN	Cost	Beneficiaries	A or B	of EPs in TIN	TIN
TIN 1	\$12,000	1,500	A: 10; B: 30	A: 25%; B: 75%	A: 35%; B: 65%
TIN 2	\$8,000	2,000	A: 21; B: 39	A: 35%; B: 65%	A: 60%; B: 40%

Step 1: To compute the national specialty-specific expected cost for a specialty across all TINs, we first calculate the numerator, which is the product of each TIN's total per capita cost times its weight (the number of attributed beneficiaries times that specialty's share of the TIN's EPs times the number of EPs of that specialty in that TIN), summed across all TINs. This sum is divided by the denominator, which is the sum across all TINs of the same weights that were used in the numerator. For this example, the national specialty-specific expected cost for Specialty A is (\$12,000 * 1,500 * 25%*10 + \$8,000 * 2,000 * 35%*21) / (1,500 * 25%*10 + 2,000 * 35%*21) = \$8,813. Similarly, the national specialty-specific expected cost for Specialty B is

(\$12,000 * 1,500 * 75%*30 + \$8,000 * 2,000 * 65%*39) / (1,500 * 75%*30 + 2,000 * 65%*39) = \$9,599.

National Specialty-Specific Expected Cost, by Specialty (step 1)

Specialty A: \$8,813

Specialty B: \$9,599

Step 2: To calculate the specialty-adjusted expected cost for each group (TIN), we would multiply the above national specialty-specific expected costs by each group's proportion of specialty-specific Part B payments. For each TIN, we compute the product of the TIN's proportion of specialty-specific Part B payments, summed across all specialty types of the TIN. In our example, the specialty-adjusted expected cost for TIN 1 would be computed as 35% * \$8,813 + 65% * \$9,599 = \$9,324. Similarly, the specialty-adjusted expected cost for TIN 2 would be 60% * \$8,813 + 40% * \$9,599 = \$9,127.

Specialty-Adjusted Expected Cost, by TIN (step 2)

TIN 1: \$9,324

TIN 2: \$9,127

Step 3: We divide the total per capita cost by the specialty-adjusted expected cost and multiply this ratio by the national average per capita cost, to convert this ratio to a dollar amount. Assuming the national average per capita cost is \$9,714, we can compute the specialty-adjusted total per capita cost for each TIN, as shown in Table 88.

Culculations							
COLUMN	A	В	C	D			
				Specialty-Adjusted			
				Total Per Capita			
		Specialty-	National	Cost: ((Column A /			
	Total Per Capita	Adjusted	Average Per	Column B) *			
TIN	Cost	Expected Cost	Capita Cost	Column C)			
TIN 1	\$12,000	\$9,324	\$9,714	\$12,502			
TIN 2	\$8,000	\$9.127	\$9.714	\$8.51/			

TABLE 88: Example of Calculating Specialty-Adjusted Total Per Capita Cost:

Calculations

The figure in the rightmost column (column D) is the specialty-adjusted total per capita cost that is used to compute a group's standardized (Z-) score. As can be seen, the specialty-adjusted total per capita cost for use in the standardized score is \$12,502 for TIN 1 and \$8,514 for TIN 2.

To illustrate the impact of the specialty adjustment methodology, we examined the distribution, by specialty, of the overall specialty-adjusted total annual per capita cost measure based on 2011 claims for group of physicians with 1 or more eligible professionals. Please see Table 66 of the CY 2014 proposed rule (78 FR 43498 through 43499) for the results of this analysis.

Under this methodology, we perform this specialty adjustment prior to computing the standardized score for all six cost measures included in the value-based payment modifier: the total per capita cost measure, the four total per capita cost measures for beneficiaries with specific conditions, and the MSPB measure. The specialty adjustment for the four condition-specific total per capita cost measures is identical to the total per capita cost measure that was described above. The specialty adjustment for the MSPB cost measure is analogous to that described above for the total per capita cost measure, except that "number of beneficiaries" is replaced with "number of episodes" and "per capita cost" is replaced with "per episode cost." Thus, each cost measure will have its own set of specialty-specific expected costs.

We considered and tested a second method, "comparability peer grouping," which constructs peer groups for each physician group practice by identifying group practices with the nearest comparable specialty mix.⁵ Under this approach, two group practices would be considered to have the same specialty mix if the share of physicians of each specialty is within a defined range for both group practices. Group practices that had a specialty mix more comparable to the practice's own mix would receive greater weight in the peer group. Among the identified peers sharing the same specialty mix, those with the most cases would receive the greatest weight.

We stated in the proposed rule that, on balance, we believe that the first method, the specialty benchmarking method, is preferable to account for the specialty composition of the group of physicians when making peer group comparisons and creating the standardized score for the cost measures for the value-based payment modifier. We also stated that this methodology allows us to apply the value-based payment modifier to smaller size groups and solo practitioners. This methodology creates one national benchmark for each cost measure. Moreover, all groups of physicians (regardless of size) are assessed against that benchmark in creating the group of physicians' standardized score. Although the calculations discussed above may be very detailed, they are transparent and we can provide each group of physicians with information on how its costs were benchmarked in its Quality and Resource Use Report.

By contrast, the second method, comparability peer grouping, would require us to develop a transparent way to define which groups of physicians are similar enough to be included in each group of physicians' peer group. This approach also creates a different

⁵ For a description of this type of method, see, for example, Margaret M. Byrne, et al., Method to Develop Health Care Peer Groups for Quality and Financial Comparisons Across Hospitals. April 2009. HSR: Health Services Research 44:2, Part I: 577-592.

benchmark for each group of physicians, which may make it more difficult for groups of physicians to understand how their costs are benchmarked.

Given these considerations, we proposed to use the first method, the specialty benchmarking method, to create the standardized score for each group's cost measures beginning with the CY 2016 value-based payment modifier. Accordingly, we proposed to amend our regulations at §414.1255 to include this policy in our cost composite methodology. We solicited comment on our proposals, including comments on ways to streamline or enhance the calculation mechanics and to make the specialty adjustments more transparent and easily understood. We also solicited comment on the alternative method, the comparability peer grouping method. We proposed to identify the specialty for each EP based on the specialty that is listed on the largest share of the EP's Part B claims. We understand that many physicians believe our current specialty designations may mask sub-specialist care furnished. We note that the procedures for obtaining a CMS specialty code are available at http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/Taxonomy.html. The following is summary of the comments we received regarding these proposals.

<u>Comment</u>: The majority of commenters supported our approach to consider physician specialty in our cost benchmarking. For example, one commenter suggested it was a significant improvement over our current methodology. Another commenter supported the refinement of the cost measure benchmarking methodology to reflect the full range of practitioners. A number of commenters expressed support for CMS refining the cost measure benchmarking methodology to account for a physician's specialty.

A number of the commenters who supported the proposal, as well as several others who neither supported nor opposed the proposal, suggested that CMS study further the specialty

adjustment to determine the impacts and potential unintended consequences prior to its inclusion so that future refinements can be made if necessary. Some commenters also asked that CMS continue to consider opportunities to compare physicians based on the type of patients they are seeing. A number of commenters urged CMS to use more subspecialty designations in the approach to adequately account for subspecialties and allow fair benchmark comparisons of cost provided by specialists. Several commenters suggested that we assign specialty designations based on a claims analysis to identify the services most typically provided by the individual (that is, the top 15 services the provider renders based on submitted claims) and assign their specialty based on the care they are most frequently providing. Another commenter suggested that we include an adjustment for site of service (for example, nursing home or long-term care facility).

Several commenters expressed concern that the CMS' proposed approach to specialty adjustment could result in a "high cost" designation for about 15 percent of some specialties (geriatricians, geriatric psychiatrists, neurosurgeons, medical and surgical oncologists), which could suggest a problem in the methodology.

While most commenters supported the specialty adjustment approach over the comparability peer grouping approach, several commenters preferred the comparability peer grouping approach. One commenter indicated that they did not have sufficient information on the criteria that CMS would use to determine comparable peer groups if the approach were implemented. Although more commenters who expressed a preference indicated that the specialty adjustment approach was more transparent, several commenters stated that the comparability peer grouping method would likely achieve greater transparency of performance, although the specialty adjustment method might be simpler to calculate. The same commenters recommended further study by CMS of the comparability peer grouping approach.

Response: We agree that the proposal is a significant improvement over our current methodology. We believe that the credibility of the quality-tiering approach depends on accurate comparisons among physicians to determine those physicians that are members of high- and low-cost groups. We proposed this method to adjust our benchmarking approach for all cost measures to create more comparable peer groups through developing a benchmark for each group based on the specialty composition of the group. We believe that this proposal improves upon our cost benchmark such that it would be appropriate once we apply the value-based payment modifier to smaller groups and solo practitioners.

We also believe that the specialty adjustment approach is adaptable to comparing physicians in solo practices, which is important because in 2017 we are required to apply the value-based payment modifier to all physicians and groups of physicians. Although we received a number of comments from sub-specialists about the lack of granularity among the available CMS physician specialties, we believe this approach is better than relying on group size alone. We also will explore ways to explain to sub-specialists the processes that we have in place to obtain a new or keep their CMS specialty designation current, and we encourage all physicians to periodically review and keep their Medicare enrollment information current including specialty designations.

We agree that an adjustment for site of service (for example, nursing home or long-term care facility) is worthwhile to consider, and will take this comment into account as a potential refinement for further exploration.

Regarding the concern that our proposed approach to specialty adjustment could result in a "high cost" designation for about 15 percent of some specialists, we would like to clarify the data on Table 66 of the proposed rule (78 FR 43498 through 43499). Table 66 provides the

percentage of physicians practicing in groups with one or more eligible professionals with at least 20 beneficiaries and does not represent all physicians within that specialty. Therefore, it is incorrect to state, for example, that Table 66 (Percentage of Physician Practicing in Groups with 1 or more Eligible Professionals with at Least 20 Beneficiaries, Classified by Cost), indicates that 14.9 percent of neurosurgeons would be classified as "high cost." Rather, 14.9 percent of neurosurgeons practicing in groups with 1 or more eligible professionals with at least 20 beneficiaries attributed to the practice would be classified as "high cost."

We believe that the comparability peer group method would require too many assumptions to be a practical alternative to consider implementing in the near term. As a result, we believe that the comparability peer group method option would be less transparent than the specialty adjustment method. Although the specialty adjustment method process is somewhat computationally involved, the calculations are straightforward, and we believe that the method is transparent. We believe that it is not necessary to delay implementing the specialty adjustment method, but we do agree that it is important to monitor the impacts of the specialty adjustment method on physician groups as the method is implemented starting with the 2016 value-based payment modifier.

After consideration of the comments received and the reasons given previously, we are finalizing our proposal to use the specialty adjustment method to create the standardized score for each group's cost measures beginning with the CY 2016 value-based payment modifier.

That is, we are refining our current peer group methodology to account for specialty mix using the specialty adjustment method. We also are finalizing our proposal to amend our regulations at \$414.1255 to include this policy in our cost composite methodology. Additionally, we are

finalizing our proposal to identify the specialty for each EP based on the specialty that is listed on the largest share of the EP's Part B claims.

5. Physician Feedback Program

Section 1848(n) of the Act requires us to provide confidential reports to physicians that measure the resources involved in furnishing care to Medicare FFS beneficiaries. Section 1848(n)(1)(A)(iii) of the Act also authorizes us to include information on the quality of care furnished to Medicare FFS beneficiaries. In the CY 2014 PFS proposed rule (78 FR 43500) we described the 2011 group and individual QRURs, which were based on CY 2011 data that we made available to certain physicians and groups of physicians. These reports provided physicians and groups of physicians with comparative performance data (both quality and resource use) that can be used to improve quality and coordinate care furnished to Medicare FFS beneficiaries. We also noted that in May 2013, we provided supplemental QRURs to group report recipients that featured episode-based costs for care of pneumonia and several acute and chronic cardiac conditions. We derived these episode-based costs using the newly developed CMS Episode Grouper software required by section 1848(n)(9)(ii) of the Act.

a. CY 2012 Group Quality and Resource Use Reports Based on CY 2012 Data and Disseminated in CY 2013.

On September 16, 2013, we made available CY 2012 QRURs to 6,779 physician groups nationwide with 25 or more EPs. These reports covered approximately 400,000 physicians practicing in large medical groups. These reports were available eight and one-half months from the close of the performance period (December 31, 2012) and 5 months from the close of the quality data submission period (March 31, 2013) – timeframes that are generally consistent with reporting programs in the commercial sector. Not only did these reports provide comparative

quality of care and cost information like in previous years, but they also previewed how the groups of physicians might fare under the value-based payment modifier. Thus, these reports were a "first look" at how the value-based payment modifier could affect their payment in the future. The QRURs provided groups of 100 or more EPs with quality-tiering information on 2012 data that they could use to decide whether to elect to be assessed under the quality-tiering approach that we adopted for the value-based payment modifier that will be applied in 2015, based on 2013 performance.

Additionally, and in response to feedback we received from prior year recipients of the QRURs, the CY 2012 QRURs contained detailed beneficiary-specific data on each group's attributed beneficiaries and their hospitalizations, and the group's associated eligible professionals. Complementing the CY 2012 QRURs are three downloadable drill down tables that provide information on each beneficiary attributed to the group and each eligible professional billing under the group's Taxpayer Identification Number (TIN). We have received very positive feedback from report recipients and expect to enhance the information we provide in future years.

Of the 6,779 physician groups nationwide with 25 or more EPs, 3,876 groups received full QRUR reports and 2,903 groups received an abbreviated report since they did not have any beneficiaries attributed to them or did not have at least 20 eligible cases for any quality or cost measure. These 2,903 groups had insufficient data on which to compute meaningful performance measures. Given the policies that we have adopted in this final rule with comment period, we anticipate that as long as a group of physicians participates in the Physician Quality Reporting System (PQRS) in 2014 and meets the criteria to avoid the 2016 PQRS payment adjustment such that group is in Category 1 (see discussion above in section III.K.4.b.), we will

be able to produce a complete QRUR, including their quality-tiering designation, in CY 2014 for most groups.

Highlights of major findings of these CY 2012 reports are as follows:

- Of the 3,876 groups for whom the quality or cost composite could be calculated based on 2012 data, over 80 percent of the groups (80.7 percent) are in the average quality and average cost tiers under the quality-tiering methodology, and thus, would not receive a payment adjustment. Approximately 8 percent of groups are in tiers that would receive an upward adjustment, and slightly less than 11 percent of groups are in tiers that would receive a downward adjustment. Among the groups eligible for an upward adjustment, 11 percent would receive an additional 1.0 percent incentive payment due to treating high-risk beneficiaries. Although we expect the results to change as physician groups understand our methodologies and seek to maximize their upward payment adjustment under the value-based payment modifier, these results are consistent with our approach to gradually implement the value-based payment modifier (see 2. Governing Principles for Physician Value-Based Payment Modifier Implementation), that is, to focus on adjusting payment for those groups that are outliers (both high and low performers).
- Groups with high quality scores performed better than groups with average and low quality scores consistently across each of the quality domains (or groupings of quality measures) as well as across the three quality outcomes measures; they also tended to have lower average cost composite scores.
- Beneficiaries that we attributed to a group of physicians received an average of five primary care services in 2012 of which, on average, 64.3 percent were provided by the group to which the beneficiary was attributed. These results suggest that our attribution approach

attributes beneficiaries to those groups of physicians that deliver the majority of a beneficiary's care and are well positioned to oversee the beneficiaries' care.

- Reliability among the quality measures was generally strong, with the self-reported PQRS measures having the greatest average reliability. Average reliabilities for all PQRS measures were more than 0.80, indicating high reliability. We note that statistical reliability scores are represented on a continuum from zero and one, with scores closer to zero indicating lower reliability while scores closer to one indicate higher reliability. While there is no universally agreed upon minimum reliability threshold, reliability scores in the 0.40-0.70 range are often considered moderate and scores greater than 0.70 are considered high. In addition to the PQRS measures, we computed 14 quality indicators from data reported in Medicare administrative claims. The average reliability of the claims-based quality indicators was lower than for the PQRS quality measures but was still quite high with 8 of the 14 measures having average reliabilities above 0.70.
- The 2012 QRURs also reported on three administrative claims-based outcome measures. The QRURs contained each group practice's performance on measures of potentially avoidable hospitalizations for ambulatory care sensitive conditions (ACSCs). These Medicare claims-based measures were derived from Prevention Quality Indicators (PQIs) developed by the Agency for Healthcare Research and Quality (AHRQ). We reported on potentially avoidable hospitalizations for two composite measures of hospital admissions for acute and chronic ACSCs. The average reliability for both ACSC composite measures across all groups was higher than 0.70. CMS also reported on a medical group practice-specific all-cause 30-day rate of acute care hospital readmissions for beneficiaries discharged from an acute care or critical access hospital. Average reliability among the subset of groups of 100+ EPs was 0.48. We

anticipate the reliability of this measure to increase as groups of physicians begin to focus on reducing unplanned readmissions.

• The ORURs include five cost-of-care measures derived from 2012 administrative claims data: total per capita costs and per capita costs for beneficiaries with four common chronic conditions: diabetes; heart failure; COPD; and CAD. The per capita (per beneficiary) cost measure assesses health care services for all Medicare FFS attributed beneficiaries and for those with chronic conditions. The measure includes all Medicare Part A and Part B costs during a calendar year and is price-standardized and risk-adjusted to account for any potential differences in costs among providers that result from circumstances beyond the physician's control. The risk adjustment process reduced the overall average per capita costs from \$12,815 to \$10,788 and compressed the range of groups' total per capita costs by 83 percent. Under our attribution rule, beneficiaries are attributed on the basis of the plurality of primary care services, to those medical group practices with the greatest potential to influence the quality and cost of care delivered to Medicare FFS beneficiaries. All group practices with 25 or more EPs achieved an average reliability score of 0.94 for the total per capita cost measure. For all groups, average reliabilities for the condition-specific cost measures ranged from 0.82 to 0.84. For larger groups with 100+ EPs, average reliability was higher for all beneficiaries (0.98), as well as for the condition-specific cost measures (0.94 for all measures).

We anticipate publicly releasing a full experience report of the CY 2012 QRURs that will include how quality-tiering would apply to groups of physicians to ensure stakeholders understand the methodologies of the value-based payment modifier. The report will be available on the Physician Feedback Program website.

b. Episode Costs and the Supplemental QRURs

Section 1848(n)(9)(A)(ii) of the Act, as added by section 3003 of the Affordable Care Act, requires CMS to develop a Medicare episode grouper by January 1, 2012, and to include episode-based costs in the QRURs. An episode of care consists of medical and/or procedural services that address a specific medical condition or procedure that are delivered to a patient within a defined time period and are captured by claims data. An episode grouper is software that organizes administrative claims data into episodes.

We have developed a CMS prototype episode grouper that classifies episodes into three categories: chronic; acute; and procedural. In the CY 2014 PFS Proposed Rule (78 FR 43502) we described the supplemental QRURs we made available to 54 large group practices in June 2013 to illustrate how the CMS Episode Grouper works and to illustrate the general approach to classifying episodes of care into these three categories. The Supplemental QRURs included episode-based costs for five clinical conditions (pneumonia, acute myocardial infarction (AMI), coronary artery disease, percutaneous coronary intervention (PCI), and coronary artery bypass graft (CABG)), which also were broken into 12 episode sub-types to account for various underlying clinical factors. We chose these episode types to gain experience with the prototype methodology of the CMS episode grouper in acute, chronic and procedural conditions.

We applied different attribution rules for each episode type (chronic, acute, or procedural) and whether the episode included a hospitalization. We believe that it is critical to attribute an episode to the group of physicians that is in the best position to oversee the quality of care furnished and the resources used to furnish that care. For chronic episodes, attribution was based on outpatient E&M visits, because these conditions are best managed in an outpatient setting. For acute inpatient-based episodes, attribution was based on Part B Physician Fee Schedule allowed amounts during the inpatient stay or percent of inpatient E&M visits; for

outpatient-based acute episodes, attribution was based on E&M visits during the episode. For procedural episodes, attribution is made to the group that includes the performing surgeon. For chronic and acute episodes, attribution required at least 35 percent of total allowed amounts or E&M visits, as applicable to the episode type. Episodes may be attributed to more than one group, although 85 percent of all episodes of any type were attributed to exactly one of the 54 medical group practices.

We also used a slightly different risk adjustment methodology to adjust the costs for the underlying risk factors for the beneficiaries with these episodes as compared to the total per capita cost measures that we have used in the CY 2012 QRURs. The CMS Episode Grouper used to generate the 2011 episode data adjusted costs for health and treatment history in the 6 months prior to the beginning of the episode. More specific risk adjusters include demographic factors (age, gender, and enrollment status), health status indicators (for example, medical condition categories from HCC model), and procedure indicators. We are continuing to examine ways to refine this approach as we develop further episode costs for additional clinical conditions.

The episodes we included in the reports had a high statistical reliability and showed a significant amount of variation across the groups and within the groups. From a reliability perspective, episodes had high or moderate reliability with six having a reliability of risk adjusted cost greater than 0.7 (range 0.78 for all AMI to 0.9 for coronary artery disease without AMI) and six between 0.5 and 0.7 (range 0.56 for PCI without AMI to 0.69 for AMI with PCI)...

There also was variation among the groups' mean episode costs compared to the national mean. For four of the five conditions, about half of the groups had a mean episode cost that was above the national episode mean, while about half were below. The exception was coronary

artery disease, for which only about 20 percent of the groups had mean episode costs below the cost of the national mean. Primary cost drivers varied by episode subtype (for example, coronary artery disease with or without myocardial infarction), and depended on whether or not the episode included inpatient hospital stays and post-acute care such as for skilled nursing facilities and rehabilitation facilities. As noted above, risk adjustment was used to account for variations in resource use beyond the medical group's control.

We plan to further develop these episode reports and to include not only additional episodes, but to make this information available to a wider set of medical group practices.

Additional clinical conditions under consideration for future QRURs include episode costs related to congestive heart failure, cardiac arrhythmias, hip fracture, osteoarthritis, cataract, glaucoma, chronic obstructive lung disease, and respiratory failure. In addition, we will begin to marry these measures of resource use with clinical quality measures included in the Physician Quality Reporting System, because resource use makes most sense in context of the quality of care furnished.

We have worked with stakeholders and specialty societies to gain input for the next iteration of the CMS Episode Grouper. We received input to examine episode attribution, handling of transfers, relook at risk adjustment, and increased drill down capacity. The CMS Episode Grouper will continue to evolve over the next few years as more experience is gained. More information about the Supplemental QRURs and a summary slide deck of findings on episode costs for medical groups eligible to receive the 2011 supplemental QRURs can be found at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-

Payment/PhysicianFeedbackProgram/Episode-Costs-and-Medicare-Episode-Grouper.html.

c. Future Plans for the Physician Feedback Reports

We will continue to develop and refine the annual QRURs in an iterative manner. As we have done in previous years, we will seek to further improve the reports by welcoming suggestions from recipients, specialty societies, professional associations, and others. We have worked with several specialty societies to develop episode costs or other cost or utilization metrics to include in the annual QRURs. We believe these efforts could be productive as we use the QRURs to not only describe how the value-based payment modifier would apply, but in addition to provide groups with utilization and other statistics that can be used for quality improvement and care coordination.

The following is a summary of the comments we received about the QRURs. We appreciate commenters' suggestions, but because we did not make any proposals relating to the QRURs, these comments were beyond the scope of the proposed rule. We will consider them as we further implement the Physician Feedback Program.

Comment: We received some comments in response to our description of updates to the QRUR program. Many commenters were very favorable about CMS' work with the physician community to develop the reports and asked that we continue to work with them to refine them. One commenter stated that, "CMS has taken large strides to improve the clarity and usability of the QRUR reports to present cost and quality information in a meaningful and clear way." The commenter also suggested that CMS reconvene the stakeholder workgroup to continue to enhance the feedback reports for 2014 and future years. Some commenters made suggestions about how to improve the reports. One commenter suggested that CMS reduce the length of the report, tailor reports to each specialty by highlighting the measures/conditions of the particular specialist receiving the report, include more details on the physician's patient population, provide recommendations on action items, and accurately identify other providers whose data may have

been used in developing the report. Another commenter asked CMS to continue to improve the timeliness and frequency of the reports. One commenter suggested that CMS should report data at the individual NPI level and roll the data up to the TIN level. Some comments suggested that CMS should give providers an opportunity to view their data before they were penalized so that they would have an opportunity to change their behavior. One commenter suggested that CMS should offer providers corrective action plans so that physicians could improve their performance before being impacted by the value based modifier. Some commenters stated that although they realized the statute requires CMS to roll out the value-based modifier to all physicians by January 1, 2017, they were concerned about the aggressive timetable for implementation and noted that providers were being impacted by several programs at once.

Response: We appreciate the commenters' responses to our description of the QRUR program and their suggestions for how to improve it. We will take these suggestions into consideration as we further implement the Physician Feedback Program.

We also welcome feedback about the recently released reports over the next few months and have several activities scheduled to allow physicians to give us their additional input. In the late summer of 2014, we plan to disseminate the QRURs based on CY 2013 data to all physicians (that is, TINs of any size) even though groups of physicians with fewer than 100 eligible professionals will not be subject to the value-based payment modifier in CY 2015. These reports will contain performance on the quality and cost measures used to score the composites and additional information to help physicians coordinate care and improve the quality of care furnished. The reports will be based on the value-based payment modifier policies that we are finalizing in this rule that will take effect January 1, 2014 and that will affect physician payment starting January 1, 2016. Groups of physicians will, therefore, have an

opportunity to determine how the policies adopted in this final rule with comment period will apply to them. After the reports are released we will again solicit feedback from physicians and continue to work with our partners to improve them. We note that physicians will have some time to determine the impact of our revised policies and revise their practices accordingly before the new policies impact them. We will study the recommendations submitted in response to this proposed rule and any later suggestions we receive and make plans to implement those that are feasible. We look forward to continue working with the physician community to improve the QRURs.

L. Updating Existing Standards for E-Prescribing under Medicare Part D

- 1. Background
- a. Legislative History

Section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173) amended title XVIII of the Act to establish a voluntary prescription drug benefit program at section 1860D-4(e) of the Act. Among other things, these provisions required the adoption of Part D e-prescribing standards. Prescription Drug Plan (PDP) sponsors and Medicare Advantage (MA) organizations offering Medicare Advantage-Prescription Drug Plans (MA-PD) are required to establish electronic prescription drug programs that comply with the e-prescribing standards that are adopted under this authority. There is no requirement that prescribers or dispensers implement e-prescribing. However, prescribers and dispensers who electronically transmit prescription and certain other information for covered drugs prescribed for Medicare Part D eligible beneficiaries, directly or through an intermediary, are required to comply with any applicable standards that are in effect.

For a further discussion of the statutory basis for this final rule with comment period and the statutory requirements at section 1860D-4(e) of the Act, please refer to section I.

(Background) of the E-Prescribing and the Prescription Drug Program proposed rule, published February 4, 2005 (70 FR 6256).

b. Regulatory History

(1) Foundation and Final Standards

We utilized several rounds of rulemaking to adopt standards for the e-prescribing program. Its first rule, which was published on November 7, 2005 (70 FR 67568), adopted three standards that were collectively referred to as the "foundation" standards. We issued a subsequent rule on April 7, 2008 (73 FR 18918) that adopted additional standards which are

referred to as "final" standards. One of these standards, the NCPDP Formulary and Benefit Standard, Implementation Guide, Version 1, Release 0 (Version 1.0, hereafter referred to as the NCPDP Formulary and Benefit 1.0) was a subject of the CY 2013 PFS final rule with comment period (77 FR 68892 at 69329) and is the subject of this final rule with comment period. Please see the "Initial Standards Versus Final Standards" discussion at 70 FR 67568 in the November 7, 2005 rule for a more detailed discussion about "foundation" and "final" standards.

(2) Updating e-Prescribing Standards

Transaction standards are periodically updated to take new knowledge, technology and other considerations into account. As CMS adopted specific versions of the standards when it adopted the foundation and final e-prescribing standards, there was a need to establish processes by which the standards could be updated or replaced over time to ensure that the standards did not hold back progress in the industry. CMS discussed these processes in its November 7, 2005 final rule (70 FR 67579).

The discussion noted that the rulemaking process will generally be used to retire, replace or adopt a new e-prescribing standard, but it also provided for a simplified "updating process" when a standard could be updated with a newer "backward-compatible" version of the adopted standard. In instances in which the user of the later version can accommodate users of the earlier version of the adopted standard without modification, it noted that notice and comment rulemaking could be waived, in which case the use of either the new or old version of the adopted standard would be considered compliant upon the effective date of the newer version's incorporation by reference in the **Federal Register**.

(3) The NCPDP Formulary and Benefit Standard in the Part D e-Prescribing Regulations

The backward compatibility concept has been used extensively to update the NCPDP SCRIPT standard in the Part D e-prescribing program, but it has not yet been used to update the adopted NCPDP Formulary and Benefit Standard. We proposed to update the NCPDP Formulary and Benefit 1.0 standard for the first time in the CY 2013 PFS proposed rule (77 FR 44722), but we did not ultimately finalize those proposals. Specifically, we proposed to recognize NCPDP Formulary and Benefit Standard 3.0 as a backward compatible version of NCPDP Formulary and Benefits 1.0 effective 60 days from the publication of the final rule, and sought comment on when we should retire NCPDP Formulary and Benefits 1.0 as well as when we should adopt NCPDP Formulary and Benefits 3.0 as the official Part D e-prescribing standard As was noted in that rule, while recognition of backward compatible versions can be done in an interim final rule in which we waive notice and comment rulemaking, other Part D e-prescribing proposals that were being made at that time required full notice and comment rulemaking, so, as we did not wish to publish two e-prescribing rules contemporaneously, we elected to forgo our usual use of our simplified updating process for backward compatible standards (in which we waive notice and comment rulemaking and go straight to final) in favor of putting all of the proposals through full notice and comment rulemaking.

2. Proposals

a. Proposed backward compatible standards

As was discussed in the CY 2013 PFS final rule with comment period (77 FR 68892), we were persuaded by commenters to refrain from retiring Formulary and Benefit Standard 1.0 until NCPDP ceased supporting it on July 1, 2014. As further noted in that rule, we believed it best to delay implementing any of our Formulary and Benefits proposals, including recognitions of NCPDP Formulary and Benefit 3.0 as a backward compatible standard, until closer to that

July 1, 2014 date. Our actions at that time were based on a belief that an extended period of use of either 3.0 or 1.0 would be ill-advised.

Having come within roughly a year of the anticipated date upon which NCPDP will cease supporting NCPDP Formulary and Benefit 1.0, we believed that it was now appropriate to repropose the recognition of NCPDP Formulary and Benefits 3.0 as a backward compatible version of Formulary and Benefits 1.0 effective 60 days after publication of a final rule until June 30, 2014, and, as discussed below, we also proposed the retirement of NCPDP Formulary and Benefits 1.0, effective July 1, 2014, and the adoption of NCPDP Formulary and Benefits 3.0 as the official Part D e-prescribing standard effective July 1, 2014.

Also, as was seen in our prior proposal to recognize backward compatibility using full notice and comment in place of the backward compatible methodology, we also proposed to require users of 3.0 to support users who are still using NCPDP Formulary and Benefit 1.0 until such time as that version is officially retired as a Part D e-prescribing standard and NCPDP Formulary and Benefit 3.0 is adopted as the official Part D e-prescribing standard.

2. Proposed Retirement of NCPDP Formulary and Benefit Standard 1.0 and adoption of NCPDP Formulary and Benefit Standard 3.0

As noted in the CY 2013 PFS proposed rule, the NCPDP Formulary and Benefits standard provides a uniform means for pharmacy benefit payers (including health plans and PBMs) to communicate a range of formulary and benefit information to prescribers via point-of-care (POC) systems. These include:

- General formulary data (for example, therapeutic classes and subclasses);
- Formulary status of individual drugs (that is, which drugs are covered);

 Preferred alternatives (including any coverage restrictions, such as quantity limits and need for prior authorization); and

• Copayment (the copayments for one drug option versus another).

Also as noted in that proposed rule, standards are updated over time to take industry feedback and new and modified business needs into account. See the CY 2013 PFS proposed rule (77 FR 45023-45024) for a full discussion of the changes to that were made to the NCPDP Formulary and Benefit 1.0 as it was updated to the NCPDP Formulary and Benefit 3.0.

As noted above, having come within roughly a year of the anticipated date upon which NCPDP will cease supporting NCPDP Formulary and Benefit 1.0, we believed that it was now appropriate to re-propose the retirement of NCPDP Formulary and Benefits 1.0, effective June 30, 2014, and also proposed the adoption of NCPDP Formulary and Benefits 3.0 as the official Part D e-prescribing standard, effective July 1, 2014.

To effectuate these proposals, we proposed to revise §423.160(b)(5). We proposed to place the existing material in a new paragraph (b)(5)(i), which would provide the official formulary and benefit standard for Part D e-prescribing until June 30, 2014. We then proposed to create a second new paragraph ((b)(5)(ii)) to recognize NCPDP Formulary and Benefit 3.0. as a backward compatible version of the official Part D e-prescribing standard (NCPDP Formulary and Benefit 1.0), effective [OFR - insert date 60 days after publication of the final rule] through June 30, 2014. Furthermore, we proposed to create a third new paragraph ((b)(5)(iii)) to reflect the retirement of NCPDP Formulary and Benefit 1.0 and the adoption of NCPDP Formulary and Benefit 3.0 as the official Part D e-prescribing standard, effective July 1, 2014. Finally, we proposed to make conforming changes to §423.160(b)(1). We solicited comment on these proposals.

The following is a summary of the comments we received regarding our proposal to recognize NCPDP Formulary and Benefit Standard 3.0 as a backward compatible version of the NCPDP Formulary and Benefit Standard 1.0, the proposed retirement of NCPDP Formulary and Benefit Standard 1.0 and the proposed adoption of NCPDP Formulary and Benefit Standard 3.0.

<u>Comment</u>: Commenters generally supported our proposal to adopt the newest version of the NCPDP Formulary and Benefit Standard 3.0 as a backward compatible version of the adopted NCPDP Formulary and Benefit 1.0 (60 days after the publication of the final rule), and the retirement of Version 1.0 as an official Part D e-prescribing standard, effective June 30, 2014.

Response: We appreciate the favorable feedback that we received on this proposal and are in agreement with the commenters who responded.

We received a total of 9 comments on our proposal as it related to the effective date of adopting Formulary and Benefit standard 3.0 on July 1, 2014 and the retirement of Formulary and Benefit Standard 1.0 on June, 30 2014 as an official Part D e-prescribing standard.

<u>Comment</u>: Some commenters agreed with our proposal stating that these types of updates are routine and reflect improvements.

Response: We appreciate the feedback we received on the proposed timeline to retire Formulary and Benefit Standard 1.0 on June, 30 2014 and to finalize adoption of the Formulary and Benefit standard 3.0 as the official Part D e-prescribing formulary and benefits standard on July 1, 2014.

<u>Comment</u>: One commenter appreciated our decision in the CY 2013 Medicare

Physicians Fee Schedule to delay retiring NCPDP Formulary and benefits Standard 1.0 and adopting the NCPDP Formulary and Benefits 3.0. They are concerned, however, with our

proposal to go forward with the proposed effective dates for the adoption of the NCPDP Formulary and Benefits Standard 3.0 and the retirement of Version 1.0 on July 1, 2014. The commenter stated that the current deadline for ICD-10 conversion is October 1, 2014 and many of their resources are devoted to the ICD-10 conversion coding as well as additional systems requirements that they assert they will need to make due to the implementation of the health insurance exchanges on January 1, 2014. They urged CMS to consider delaying the adoption of the NCPDP Formulary and Benefits 3.0 update until early 2015. They stated that this would provide stakeholders with sufficient time to be able to ensure adequate time to address these issues that are coming online in 2014.

Response: We appreciate the comment, but we disagree with the commenter's concerns about the conversion to ICD-10 on October 1, 2014. On October 1, 2014, the ICD-9 code sets used to report medical diagnoses and inpatient procedures will be replaced by ICD-10 code sets. The transition to ICD-10 is required for everyone subject to the Health Insurance Portability Accountability Act (HIPAA). Industry has had 3 years to prepare for this new requirement and should have already started preparing for the conversion to ICD-10, so we do not believe that the conversion to the NCPDP Formulary and Benefit Standard 3.0 will present an undue added burden.

Furthermore, we do not agree with commenter's assertion that the implementation of the health care exchanges on January 1, 2014 will impose burdens that would affect an entity's ability to implement the NCPDP Formulary and Benefit Standard 3.0 on July 1, 2014.

Furthermore, we would note that the health care exchanges actually went live on October 1, 2013, with coverage for those who enroll beginning as early as January 1, 2014. Any system changes that may be needed will therefore have to have been made by October 1, 2013, or

January 1, 2014, depending on what systems the commenter may have been referencing. As such, we do not see how the implementation of the health care exchanges would have any impact on the proposed implementation date for the NCPDP Formulary and Benefit Standard 3.0 on July 1, 2014.

<u>Comment</u>: Two commenters recommended that we delay the proposed June 30, 2014 and July 1, 2014 effective dates 12 months. One commenter stated that 7 months is insufficient time for safe and efficient development and implementation. They asserted that, if the proposed rule goes into effect, the proposed dates would leave EHR developers and EHR users approximately 7 months to do all of the following:

- Complete development to support for the new standard.
- Test the configuration required for the new standard.
- Move this configuration into production.

Another commenter urged CMS to consider an 18-month timeframe between the effective date of this final rule and the compliance date for those subject to the rule. The commenter stated that 18 months would allow EHR developers and healthcare organizations to include the upgrade with other work already in progress for programs such as Meaningful Use and the ICD-10 transition. The commenter recommended the retirement of the use of the current NCPDP Formulary and Benefit 1.0 standard June 30, 2015 and the adoption of NCPDP Formulary and Benefit 3.0 as the official Part D e-prescribing formulary and benefits standard on July 1, 2015.

Another commenter recommended that entities be allowed to use NCPDP Formulary Benefit Version 1.0 or Version 3.0 during a transition period that would end June 30, 2015, and

that the NCPDP Formulary and Benefit 3.0 should become the official Part D e-prescribing formulary and benefits standard effective July 1, 2015.

Response: We appreciate the comments but do not believe that there is a compelling reason to allow use of NCPDP Formulary Benefit Version 1.0 or Version 3.0 through June 30, 2015, or to wait to make NCPDP Formulary and Benefit 3.0 the official Part D standard until July 1, 2015. As we have stated in the past, we do not think it is advisable to have extended periods in which either an adopted standard or a backward compatible version of that standard may be used. We believe that allowing the extended use of Version 3.0 as a backward compatible version of Version 1.0 would create confusion.

We understand that our regulations should impose the minimum burden possible on the industry; we therefore re-evaluated our initial timeline proposal in light of recommendations from commenters. We concluded that a July 1, 2014 effective date may be an aggressive timeline for the implementation of the updated NCPDP Formulary and Benefits 3.0 standard, and that some of the commenters have made valid arguments in regards to moving the effective dates back from what we originally proposed.

Commenters have convinced us that if we were to finalize the original timelines as proposed, the industry may not have time to ensure that all of the changes, testing, and implementation activities for the move to Version 3.0 will be completed in time. At the same time, however, we believe that the suggested 18 month delay in effective date is too long. We believe a suitable compromise would be to delay the effective date of our proposals to retire Version 1.0 and to adopt Version 3.0 as the official Part D e-prescribing standard by moving the originally anticipated effective date of this final rule to early 2015. As such, we will retire the Version 1.0 effective February 28, 2015, and adopt Version 3.0 as the official Part D e-

prescribing standard effective March 1, 2015. Furthermore, Version 3.0 will be recognized as a backward compatible version of the adopted Version 1.0 from [**OFR** - **insert date 60 days from publication in Federal Register**] through February 28, 2015.

Comment: We received a comment from NCPDP that asked for clarification of our statement in the proposed rule regarding the anticipated date upon which NCPDP would cease supporting NCPDP Formulary and Benefit 1.0. NCPDP stated that they do not intend to cease to support NCPDP Formulary and Benefit Standard Version 1.0, meaning that it will always be included as a a version in the listing of NCPDP publications. They acknowledged that versions may be retired over time as the industry ceases active use of them, but, as in this case, regulations would drive which version would be the appropriate version to be used.

Response: We appreciate the comment from NCPDP clarifying that they will keep NCPDP Formulary and Benefits 1.0 in its list of publications available to its membership.

As a result of the comments, we believe that some of the commenters have made valid arguments in regards to moving the effective dates back from what we originally proposed. We believe a suitable compromise would be to delay the effective date of our proposals to retire Version 1.0 on February 28, 2015 and to adopt Version 3.0 as the official Part D e-prescribing standard on March 1, 2015. This would allow industry adequate time to implement the necessary changes and testing needed to implement. That means that the retirement of Version 1.0 will be effective February 28, 2015, and the adoption of Version 3.0 as the official Part D e-prescribing standard will be effective March 1, 2015.

We are therefore finalizing recognition of the NCPDP Formulary and Benefits Standard 3.0 as a backward compatible version of NCPDP Formulary and Benefits Standard 1.0 as of the effective date of this final rule with comment period effective [**OFR** - **insert date 60 days after**

publication in the Federal Register], the retireent of NCPDP Formulary and Benefits Standard Version 1.0 effective February 28, 2015 and the adoption of NCPDP Formulary and Benefits Standard Version 3.0 as the official Part D e-Prescribing Standard effective March 1, 2015. To effectuate this, we are revising §423.160(b)(5) to redesignate the current (b)(5) as (b)(5)(i), which will cover prior to [OFR—Insert date 59 days after publication in the Federal Register], and adding a new (b)(5)(ii) (which will cover [OFR—Insert date 60 days after publication in the Federal Register] until February 28, 2015) and (b)(5)(iii) (which will cover March 1, 2015 and beyond). Section (b)(5)(ii) will be applicable to the period in which Version 3.0. will be recognized as a backward compatible version of Version 1.0, during which time Version 1.0 will remain the official Part D e-prescribing standard. Section 423.160(b)(5)(iii) will be applicable to the period in which Version 3.0 is the official Part D e-prescribing standard.

We will also amend the incorporation by reference in the Part D e-prescribing regulations by adding a reference to the NCPDP Formulary and Benefit Standard 3.0 at §423.160(c)(1)(vi). Finally, we will make conforming changes to §423.160(b)(1) to reflect the changes to §423.160(b)(5).

M. Discussion of Budget Neutrality for the Chiropractic Services Demonstration

Section 651 of MMA requires the Secretary to conduct a demonstration for up to 2 years to evaluate the feasibility and advisability of expanding coverage for chiropractic services under Medicare. Current Medicare coverage for chiropractic services is limited to treatment by means of manual manipulation of the spine to correct a subluxation described in section 1861(r)(5) of the Act provided such treatment is legal in the state or jurisdiction where performed. The demonstration expanded Medicare coverage to include: "(A) care for neuromusculoskeletal conditions typical among eligible beneficiaries; and (B) diagnostic and other services that a chiropractor is legally authorized to perform by the state or jurisdiction in which such treatment is provided." The demonstration was conducted in four geographically diverse sites, two rural and two urban regions, with each type including a Health Professional Shortage Area (HPSA). The two urban sites were 26 counties in Illinois and Scott County, Iowa, and 17 counties in Virginia. The two rural sites were the States of Maine and New Mexico. The demonstration, which ended on March 31, 2007, was required to be budget neutral as section 651(f)(1)(B) of MMA mandates the Secretary to ensure that "the aggregate payments made by the Secretary under the Medicare program do not exceed the amount which the Secretary would have paid under the Medicare program if the demonstration projects under this section were not implemented."

In the CY 2006, 2007, and 2008 PFS final rules with comment period (70 FR 70266, 71 FR 69707, 72 FR 66325, respectively), we included a discussion of the strategy that would be used to assess budget neutrality (BN) and the method for adjusting chiropractor fees in the event the demonstration resulted in costs higher than those that would occur in the absence of the demonstration. We stated that BN would be assessed by determining the change in costs based

on a pre-post comparison of total Medicare costs for beneficiaries in the demonstration and their counterparts in the control groups and the rate of change for specific diagnoses that are treated by chiropractors and physicians in the demonstration sites and control sites. We also stated that our analysis would not be limited to only review of chiropractor claims because the costs of the expanded chiropractor services may have an impact on other Medicare costs for other services.

In the CY 2010 PFS final rule with comment period (74 FR 61926), we discussed the evaluation of this demonstration conducted by Brandeis University and the two sets of analyses used to evaluate BN. In the "All Neuromusculoskeletal Analysis," which compared the total Medicare costs of all beneficiaries who received services for a neuromusculoskeletal condition in the demonstration areas with those of beneficiaries with similar characteristics from similar geographic areas that did not participate in the demonstration, the total effect of the demonstration on Medicare spending was \$114 million higher costs for beneficiaries in areas that participated in the demonstration. In the "Chiropractic User Analysis," which compared the Medicare costs of beneficiaries who used expanded chiropractic services to treat a neuromusculoskeletal condition in the demonstration areas, with those of beneficiaries with similar characteristics who used chiropractic services as was currently covered by Medicare to treat a neuromusculoskeletal condition from similar geographic areas that did not participate in the demonstration, the total effect of the demonstration on Medicare spending was a \$50 million increase in costs.

As explained in the CY 2010 PFS final rule, we based the BN estimate on the "Chiropractic User Analysis" because of its focus on users of chiropractic services rather than all Medicare beneficiaries with neuromusculoskeletal conditions, as the latter included those who did not use chiropractic services and who may not have become users of chiropractic services

even with expanded coverage for them (74 FR 61926 through 61927). Users of chiropractic services are most likely to have been affected by the expanded coverage provided by this demonstration. Cost increases and offsets, such as reductions in hospitalizations or other types of ambulatory care, are more likely to be observed in this group.

As explained in the CY 2010 PFS final rule (74 FR 61927), because the costs of this demonstration were higher than expected and we did not anticipate a reduction to the PFS of greater than 2 percent per year, we finalized a policy to recoup \$50 million in expenditures from this demonstration over a 5-year period, from CYs 2010 through 2014 (74 FR 61927). Specifically, we are recouping \$10 million for each such year through adjustments to the chiropractic CPT codes. Payment under the PFS for these codes will be reduced by approximately 2 percent. We believe that spreading this adjustment over a longer period of time will minimize its potential negative impact on chiropractic practices.

For the CY 2013 PFS, our Office of the Actuary (OACT) estimated chiropractic expenditures to be approximately \$470 million, which reflected the statutory 26.5 percent reduction to PFS payments scheduled to take effect that year. The statute was subsequently amended to impose a zero percent PFS update for CY 2013 instead of the 26.5 percent reduction. In large part because of the change in the PFS update, OACT now estimates CY 2013 chiropractic expenditures to be approximately \$580 million. Because of the change in projected chiropractic expenditures, we now expect to recoup approximately \$11.6 million from the 2 percent payment reduction for chiropractic CPT codes in CY 2013.

We expect to complete the required BN adjustment by recouping the remainder of the chiropractic expenditures in CY 2014. For each year of this recoupment, we have provided OACT's projected chiropractic expenditures based on previous year's data. While OACT's

projections have included the statutory reductions to physician payments, the statute was amended in each year to avoid these reductions. As a result, Medicare expenditures for chiropractic services during the recoupment were higher than the OACT projections.

Chiropractic services expenditures during the recoupment period have been as follows: \$540 million in 2010; \$520 million in 2011; and \$580 million in 2012. In total, CMS recouped \$32.8 million over the years of 2010, 2011 and 2012. OACT now projects chiropractic expenditures to be approximately \$580 million in 2013. A 2 percent recoupment percentage for chiropractic services would result in approximately \$11.6 million in 2013. For the years 2010 through 2013, CMS would have recouped approximately \$44.4 million of the \$50 million required for budget neutrality.

In 2014, CMS is reducing the recoupment percentage for the chiropractic codes to ensure the recoupment does not exceed the \$50 million required for budget neutrality. OACT estimates chiropractic expenditures in CY 2014 will be approximately \$560 million based on Medicare spending for chiropractic services for the most recent available year and reflecting an approximate 20 percent reduction to the physician fee schedule conversion factor scheduled to take effect under current law. CMS plans to recoup the remaining funds, approximately \$5.6 million, and will reduce chiropractic CPT codes (CPT codes 98940, 98941, and 98942) by the appropriate percentage. We will reflect this reduction only in the payment files used by the Medicare contractors to process Medicare claims rather than through adjusting the RVUs. Avoiding an adjustment to the RVUs preserves the integrity of the PFS, particularly since many private payers also base payment on the RVUs.

We received no comments regarding this provision of the PFS. Therefore, as finalized in the CY 2010 PFS regulation and reiterated in the CYs 2011 through 2013 PFS regulations, we

are implementing this methodology and recouping excess expenditures under the chiropractic services demonstration from PFS payment for the chiropractor codes as set forth above. This recoupment addresses the statutory requirement for BN and appropriately impacts the chiropractic profession that is directly affected by the demonstration. We intend for CY 2014 to be the last year of this required recoupment.

N. Physician Self-Referral Prohibition: Annual Update to the List of CPT/HCPCS Codes

1. General

Section 1877 of the Act prohibits a physician from referring a Medicare beneficiary for certain designated health services (DHS) to an entity with which the physician (or a member of the physician's immediate family) has a financial relationship, unless an exception applies.

Section 1877 of the Act also prohibits the DHS entity from submitting claims to Medicare or billing the beneficiary or any other entity for Medicare DHS that are furnished as a result of a prohibited referral.

Section 1877(h)(6) of the Act and §411.351 of our regulations specify that the following services are DHS:

- Clinical laboratory services
- Physical therapy services
- Occupational therapy services
- Outpatient speech-language pathology services
- Radiology and certain other imaging services
- Radiation therapy services and supplies
- Durable medical equipment and supplies
- Parenteral and enteral nutrients, equipment, and supplies
- Prosthetics, orthotics, and prosthetic devices and supplies
- Home health services
- Outpatient prescription drugs
- Inpatient and outpatient hospital services

2. Annual Update to the Code List

a. Background

In §411.351, we specify that the entire scope of four DHS categories is defined in a list of CPT/HCPCS codes (the Code List), which is updated annually to account for changes in the most recent CPT and HCPCS Level II publications. The DHS categories defined and updated in this manner are:

- Clinical laboratory services.
- Physical therapy, occupational therapy, and outpatient speech-language pathology services.
- Radiology and certain other imaging services.
- Radiation therapy services and supplies.

The Code List also identifies those items and services that may qualify for either of the following two exceptions to the physician self-referral prohibition:

- EPO and other dialysis-related drugs (§411.355(g)).
- Preventive screening tests, immunizations, or vaccines (§411.355(h)).

The definition of DHS at §411.351 excludes services that are reimbursed by Medicare as part of a composite rate (unless the services are specifically identified as DHS and are themselves payable through a composite rate, such as home health and inpatient and outpatient hospital services). Effective January 1, 2011, EPO and dialysis-related drugs furnished in or by an ESRD facility (except drugs for which there are no injectable equivalents or other forms of administration), have been reimbursed under a composite rate known as the ESRD prospective payment system (ESRD PPS) (75 FR 49030). Accordingly, EPO and any dialysis-related drugs that are paid for under ESRD PPS are not DHS and are not listed among the drugs that could

qualify for the exception at §411.355(g) for EPO and other dialysis-related drugs furnished in or by an ESRD facility.

Drugs for which there are no injectable equivalents or other forms of administration were scheduled to be paid under ESRD PPS beginning January 1, 2014 (75 FR 49044). However, on January 3, 2013, Congress enacted the American Taxpayer Relief Act of 2012 (ATRA), (Pub. L. 112-240), which will delay payment of these drugs under ESRD PPS until January 1, 2016. In the meantime, such drugs furnished in or by an ESRD facility are not reimbursed as part of a composite rate and thus, are DHS. For purposes of the exception at §411.355(g), only those drugs that are required for the efficacy of dialysis may be identified on the List of CPT/HCPCS Codes as eligible for the exception. As we have explained previously in the 2010 PFS final rule (75 FR 73583), we do not believe that any drugs for which there are no injectable equivalents or other forms of administration are required for the efficacy of dialysis. We therefore have not included any such drugs on the list of drugs that can qualify for the exception.

The Code List was last updated in Addendum J of the CY 2013 PFS final rule with comment period.

b. Response to Comments

We received no public comments relating to the Code List that became effective January 1, 2013.

c. Revisions Effective for 2014

The updated, comprehensive Code List effective January 1, 2014, appears as Addendum K in this final rule with comment period and is available on our website at http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/List of Codes.html.

Additions and deletions to the Code List conform it to the most recent publications of

CPT and HCPCS Level II, and to changes in Medicare coverage policy and payment status.

Tables 89 and 90 identify the additions and deletions, respectively, to the comprehensive Code List that become effective January 1, 2014. Tables 89 and 90 also identify the additions and deletions to the list of codes used to identify the items and services that may qualify for the exceptions in §411.355(g) (regarding dialysis–related outpatient prescription drugs furnished in or by an ESRD facility) and in §411.355(h) (regarding preventive screening tests, immunizations, and vaccines).

We will consider comments regarding the codes listed in Tables 89 and 90.

Comments will be considered if we receive them by the date specified in the "DATES" section of this final rule with comment period. We will not consider any comment that advocates a substantive change to any of the DHS defined in §411.351.

TABLE 89: Additions to the Physician Self-Referral List of CPT^{1/}HCPCS Codes

CLINICAL LABORATORY SERVICES
{No additions}
PHYSICAL THERAPY, OCCUPATIONAL THERAPY, AND OUTPATIENT
SPEECH-LANGUAGE PATHOLOGY SERVICES
92521 Evaluation of speech fluency
92522 Evaluate speech production
92523 Speech sound lang comprehen
92524 Behavral qualit analys voice
97610 Low frequency non-thermal US
G0460 Autologous PRP for ulcers
RADIOLOGY AND CERTAIN OTHER IMAGING SERVICES
97610 Low frequency non-thermal US
0330T Tear film img uni/bi w/i&r
0331T Heart symp image plnr
0332T Heart symp image plnr spect
0346T+ Ultrasound elastography
A9520 Tc99 Tilmanocept diag 0.5mci
A9586 Florbetapir F18
C9734 U/S trtmt, not leiomyomata
RADIATION THERAPY SERVICES AND SUPPLIES
C9734 U/S trtmt, not leiomyomata
EPO AND OTHER DIALYSIS-RELATED DRUGS
{No additions}
PREVENTIVE SCREENING TESTS, IMMUNIZATIONS AND
VACCINES
90661 Flu vacc cell cult prsv free
90673 Flu vacc RIV3 no preserv
90685 Flu vac no prsv 4 val 6-35 m
90686 Flu vac no prsv 4 val 3 yrs+
90688 Flu vacc 4 val 3 yrs plus im

¹CPT codes and descriptions only are copyright 2013 AMA. All rights are reserved and applicable FARS/DFARS clauses apply.

TABLE 90: Deletions from the Physician Self-Referral List of CPT^{1/}HCPCS Codes

CLINICAL LABORATORY SERVICES
{No deletions}
PHYSICAL THERAPY, OCCUPATIONAL THERAPY, AND OUTPATIENT
SPEECH-LANGUAGE PATHOLOGY SERVICES
0183T Wound Ultrasound
92506 Speech/hearing evaluation
RADIOLOGY AND CERTAIN OTHER IMAGING SERVICES
{No deletions}
RADIATION THERAPY SERVICES AND SUPPLIES
{No deletions}
EPO AND OTHER DIALYSIS-RELATED DRUGS
{No deletions}
PREVENTIVE SCREENING TESTS, IMMUNIZATIONS AND
VACCINES
{No deletions}

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IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
 - The accuracy of our estimate of the information collection burden.
 - The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

In the CY 2014 PFS proposed rule (78 FR 43506), we solicited public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs). No comments were received.

A. ICRs Regarding Medical Services Coverage Decisions that Relate to Health Care Technology (§405.211)

Over the past 18 years, there have been approximately 4000 IDE studies approved that are potentially coverable by Medicare, averaging to about 222 per year. If the sponsor requests a second review, the documents will have to be sent again. We estimate that this may happen 5-8 percent of the time. Adding another 8 percent brings the total estimate to approximately 240 requests per year.

To derive average costs, we used data from the U.S. Bureau of Labor Statistics for all salary estimates. The salary estimates include the cost of fringe benefits, calculated at 35 percent of salary, which is based on the May 2013 Employer Costs for Employee Compensation report by the Bureau. The burden associated with the requirements under §405.211 is the time and effort it will take a study sponsor that is seeking Medicare coverage related to an FDA-approved Category A or B IDE to prepare the request and supporting documents (a copy of each of the following: FDA approval letter of the IDE, IDE study protocol, IRB approval letter, NCT number, and supporting materials (as needed).

For the most part, the documents are copies of communications between the study sponsor and the FDA. Accordingly, we estimate that it will take 1 to 2 hours for an executive administrative assistant in a medical device company to prepare the required information. We estimate that for 240 requests per year, that the total time to be expended by all potential study sponsors is estimated to be between 240 to 480 hours. In deriving costs to the public, we used the Bureau of Labor Statistics May 2012 estimate of \$24.14 + 35% in fringe benefits for estimated hourly wage of \$32.59 for an executive administrative assistant (occupation code 43-6011). We estimate the cost to be between \$7.822 - \$15,643 per study, for 222 potential IDE study sponsors plus a potential 19 additional submissions. If the average time of a study is 2 years, the annualized cost is \$3.911 - \$15,643 years applications or \$16.30 - \$39.59 per study.

The higher figure is used for the burden calculation in our PRA submission to OMB. The preceding requirements and burden estimates will be submitted to OMB under OCN 0938-New (CMS-10511).

B. ICRs Regarding the Physician Quality Reporting System (PQRS) (§414.90)

We are making certain revisions to §414.90, primarily to include our final policies for the qualified clinical data registry option. Please note that we solicited but received no specific public comment either supporting or opposing the impact statements related to our proposals for the PQRS. Therefore, our estimates below are based on the final requirements for participation in the PQRS in 2014.

We are revising §414.90(b), (c), and (e) and adding new paragraphs (h) and (j) of §414.90 to indicate our requirements for the qualified clinical data registry option, including specifying the criteria for satisfactory participation in a qualified clinical data registry for the 2014 PQRS incentive and 2016 PQRS payment adjustment. In addition, we are revising §414.90(g) and newly redesignated §414.90(i) to indicate the addition of a new PQRS reporting mechanism for group practices – the CMS-certified survey vendor – as well as to specify the satisfactory reporting criteria for the 2014 PQRS incentive and 2016 PQRS payment adjustment. While the sections contain information collection requirements regarding the input process and the endorsement of consensus-based quality measures, this rule does not revise any of the information collection requirements or burden estimates that are associated with those provisions.

The preamble of this final rule with comment period discusses the background of the PQRS, provides information about the measures and reporting mechanisms that are available to eligible professionals and group practices who choose to participate in 2014, and provides the criteria for satisfactory reporting data on quality measures in 2014 (for the 2014 PQRS incentive and the 2016 PQRS payment adjustment). Below are our burden estimates for participating in the PQRS in 2014 which are subject to OMB review/approval under OCN 0938-1059. (CMS-10276).

1. Participation in the 2014 PQRS

In the CY 2013 PFS final rule with comment period, we provided estimates related to the impact of the requirements we finalized for the PQRS for 2014. Since we are adding and modifying certain requirements for the 2014 PQRS, this section modifies the impact statement provided in the CY 2013 PFS final rule with comment period for reporting in 2014. Please note that we will base our estimates on information found in the 2011 Physician Quality Reporting System and eRx Reporting Experience and Trends (hereinafter "the PQRS Reporting Experience"). This report contains the latest data we have gathered on PQRS participation. The PQRS Reporting Experience is available at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/index.html?redirect=/PQRS/. According to the 2011 Reporting Experience Report, over 1 million professionals were eligible to participate in the PQRS. A total of \$261,733,236 in PQRS incentives was paid by CMS for the 2011 program year, which encompassed 26,515 practices that included 266,521 eligible professionals (or approximately 27 percent of the professionals eligible to participate). The average incentive earned for PQRS in 2011 per each individually-participating eligible professional was \$1,059.

As we noted in our impact statement last year, we expect that, due to the implementation of payment adjustments beginning in 2015, participation in the PQRS will rise incrementally to approximately 300,000 eligible professionals and 400,000 eligible professionals in 2013 and 2014, respectively. We believe our estimate of 400,000 eligible professionals participating in PQRS in 2014 remains accurate.

With respect to the estimated amount of incentives earned, for 2014, eligible professionals can earn a 0.5 percent incentive (that is, a bonus payment equal to 0.5 percent of the total allowed part B charges for covered professional services under the PFS furnished by the

eligible professional during the reporting period) for satisfactory reporting. Based on information drawn from the 2011 Reporting Experience and our participation estimate, we believe that, out of the 400,000 eligible professionals we expect to participate in the PQRS in 2014, the PQRS will distribute 2014 incentives to approximately (27 percent of 1 million eligible professionals) 270,000 eligible professionals. At \$1,059 per eligible professional, the PQRS will distribute approximately \$286 million in incentive payments for 2014. We believe these incentive payments will help offset the cost eligible professionals may undertake for participating in the PQRS for the applicable year.

We note that the total burden associated with participating in the PQRS is the time and effort associated with indicating intent to participate in the PQRS, if applicable, and submitting PQRS quality measures data. When establishing these burden estimates, we assume the following:

- For an eligible professional or group practice using the claims, qualified registry, qualified clinical data registry, or EHR-based reporting mechanisms, we assume that the eligible professional or group practice will attempt to report quality measures data with the intention of earning the 2014 PQRS incentive and not simply to avoid the 2016 PQRS payment adjustment. Therefore, an eligible professional or group practice will report on 9 measures.
- With respect to labor costs, we believe that a billing clerk will handle the administrative duties associated with participating, while a computer analyst will handle duties related to reporting PQRS quality measures. According to the Bureau of Labor Statistics, the mean hourly wage for a billing clerk is approximately \$16/hour whereas the mean hourly wage for a computer analyst is approximately \$40/hour.

Please note that these estimates do not reflect total costs estimates for participating in PQRS, but rather the adjustments (+/-) associated with the changes for 2014.

2. Burden Estimate on Participation in the 2014 PQRS – New Individual Eligible Professionals: Preparation

For an eligible professional who wishes to participate in PQRS as an individual, the eligible professional need not indicate his/her intent to participate. Instead, the eligible professional may simply begin reporting quality measures data. Therefore, these burden estimates for individual eligible professionals participating in PQRS are based on the reporting mechanism the individual eligible professional chooses. However, we believe a new eligible professional or group practice will spend 5 hours—which includes 2 hours to review PQRS measures list, review the various reporting options, and select a reporting option and measures on which to report and 3 hours to review the measure specifications and develop a mechanism for incorporating reporting of the selected measures into their office work flows. Therefore, we believe that the initial administrative costs associated with participating in PQRS will be approximately \$80 (\$16/hour x 5 hours).

Burden Estimate on Participation in the 2014 PQRS via the Claims-based Reporting
 Mechanism – Individual Eligible Professionals

Historically, the claims-based reporting mechanism is the most widely used reporting mechanism in PQRS. In 2011, 229,282 of the 320,422 eligible professionals (or 72 percent of eligible professionals) used the claims-based reporting mechanism. In the CY 2013 PFS final rule with comment period, we estimated that approximately 320,000 eligible professionals, whether participating individually or in a group practice, will participate in PQRS by CY 2014

(77 FR 69338). We believe this estimate should be further modified to reflect a lower participation estimate in 2014 for the following reasons:

- We are eliminating the option to report measures groups via claims for the 2014 PQRS incentive and 2016 PQRS payment adjustment.
- We are increasing the number of measures that an eligible professional must report to meet the criteria for satisfactory reporting for the 2014 PQRS incentive from 3 measures to 9, but lower the reporting threshold to 50 percent.
- We are removing the claims-based reporting mechanism as an option for reporting certain individual quality measures.

We estimate that approximately 230,000 eligible professionals (that is, the same number of eligible professionals who participated in the PQRS using the claims-based reporting mechanism in 2011) will participate in the PQRS using the claims-based reporting mechanism. Therefore, we estimate that approximately 58 percent of the eligible professionals participating in PQRS will use the claims-based reporting mechanism.

With respect to an eligible professional who participated in PQRS via claims, the eligible professional must gather the required information, select the appropriate quality data codes (QDCs), and include the appropriate QDCs on the claims they submitted for payment. PQRS will collect QDCs as additional (optional) line items on the existing HIPAA transaction 837-P and/or CMS Form 1500 (OCN 0938-0999). Based on our experience with Physician Voluntary Reporting Program (PVRP), we continue to estimate that the time needed to perform all the steps necessary to report each measure via claims ranges from 0.25 minutes to 12 minutes, depending on the complexity of the measure. Therefore, the time spent reporting 9 measures ranges from 2.25 minutes to 108 minutes. Using an average labor cost of \$40/hour, we estimated that the

time cost of reporting for an eligible professional via claims ranges from \$1.50 (2.25 minutes or 0.0375 hours x \$40/hour) to \$72.00 (108 minutes or 1.8 hours x \$40/hour) per reported case. With respect to how many cases an eligible professional will report when using the claims-based reporting mechanism, we established that an eligible professional needs to report on 50 percent of the eligible professional's applicable cases. The actual number of cases on which an eligible professional reports varies depending on the number of the eligible professional's applicable cases. However, in prior years, when the reporting threshold was 80 percent for claims-based reporting, we found that the median number of reporting cases for each measure was 9. Since we reduced the reporting threshold to 50 percent, we estimate that the average number of reporting cases for each measure will be reduced to 6. Based on these estimates, we estimate that the total cost of reporting for an eligible professional choosing the claims-based reporting mechanism ranges from (\$1.50/per reported case x 6 reported cases) \$9.00 to (\$72.00/reported case x 6 reported cases) \$432.

4. Burden Estimate on PQRS Participation in CY 2014 via the Qualified Registry, Qualified Clinical Data Registry, or EHR Reporting Mechanisms

We noted previously that we estimated a significant reduction in the number of eligible professionals using the claims-based reporting mechanism to report PQRS quality measures data in 2014. Specifically, we estimated that approximately 230,000 eligible professionals would participate in the PQRS using the claims-based reporting mechanism in 2014. Therefore, we estimated that the remainder of the eligible professionals (170,000) would participate in PQRS using either the qualified registry, qualified clinical data registry, EHR (using either a direct EHR or EHR data submission vendor), or the GPRO web interface reporting mechanisms.

With respect to participation in a qualified registry or qualified clinical data registry, we are combining our estimates for the number of eligible professionals we believe will use the qualified registry and qualified clinical data registry reporting mechanisms for the 2014 PQRS incentive and 2016 PQRS payment adjustment. We are combining these estimates because we believe that, at least for this initial year, many of the registries that become qualified clinical data registries will also be existing qualified registries. As such, we anticipate there will be little to no additional, new registries that will submit quality measures data on behalf of eligible professionals to the PQRS for purposes of the 2014 PQRS incentive and 2016 PQRS payment adjustment.

In 2011, approximately 50,215 (or 16 percent) of the 320,422 eligible professionals participating in PQRS used the registry-based reporting mechanism. We believe the number of eligible professionals and group practices using a qualified registry or qualified clinical data registry would remain the same, given that eligible professionals use registries for functions other than PQRS and therefore, would not obtain a qualified registry or qualified clinical data registry solely for PQRS reporting in CY 2014. Please note that this estimate would include participants choosing the new qualified clinical data registry reporting mechanism. At least in its initial stage, we believe most of the vendors that would be approved to be a qualified clinical data registry would be existing qualified registries.

In 2011, 560 (or less than 1 percent) of the 320,422 eligible professionals participating in PQRS used the EHR-based reporting mechanism. We believe the number of eligible professionals and group practices using the EHR-based reporting mechanism will increase as eligible professionals become more familiar with EHR products and more eligible professionals participate in programs encouraging use of an EHR, such as the EHR Incentive Program. In

particular, we believe eligible professionals and group practices will transition from using the claims-based to the EHR-based reporting mechanisms. We estimate that approximately 50,000 eligible professionals (which is the same estimate as we are providing for eligible professionals who use the qualified registry or qualified clinical data registry-based reporting mechanisms), whether participating as an individual or part of a group practice, will use the EHR-based reporting mechanism in CY 2014.

With respect to an eligible professional or group practice who participated in PQRS via a qualified registry, qualified clinical data registry, direct EHR product, or EHR data submission vendor's product, we believe there will be little to no burden associated for an eligible professional to report quality measures data to CMS, because the eligible professional will select a reporting mechanism to submit the quality measures data on the eligible professional's behalf. Therefore, the actual reporting is performed by the reporting mechanism, not the eligible professional.

While we noted that there may be start-up costs associated with purchasing a qualified registry, direct EHR product, or EHR data submission vendor, we believe that an eligible professional or group practice will not use a qualified registry, qualified clinical data registry, or EHR data submission vendor product, or purchase a direct EHR product, solely for the purpose of reporting PQRS quality measures. Therefore, we have not included the cost of using a qualified registry, qualified clinical data registry, or EHR data submission vendor product, or purchasing a direct EHR product in our burden estimates.

5. Burden Estimate on PQRS Participation in CY 2014 – Group Practices

Please note that with the exception of the estimates associated with a group selfnominating to participate in the PQRS under the group practice reporting option (GPRO), this

section only contains our estimates for group practices who participate in the PORS under the GPRO via the GPRO web interface reporting mechanism. We note that the burden associated with reporting quality measures for group practices using the qualified registry or EHR-based reporting mechanisms are included in the estimates we provided for the qualified registry or EHR-based reporting mechanisms above. According to the 2011 PQRS and eRx Experience report, of the 101 practices participating in the GPRO, 54 of these practices participated using the GPRO web interface (formerly referred to as "the GPRO tool"). We estimate that because are applying the value-based payment modifier to all group practices of 10 or more eligible professionals, we estimate that approximately 30 percent of such group practices, or about 5,100 group practices, will participate in the PQRS under the GPRO for purposes of the 2014 PQRS incentive and the 2016 payment adjustment. In addition, we estimate that of the 5,100 group practices that are expected to self-nominate to participate in the PORS under the GPRO. approximately 70,000 eligible professionals (that is, the remainder of the eligible professionals not participating in PQRS using the claims, qualified registry, qualified clinical data registry, or EHR-based reporting mechanisms), representing about 30 percent of the groups with 100 or more eligible professionals (or about 340 groups), will choose to participate in PQRS using the GPRO web interface for purposes of the 2014 PQRS incentive and the 2016 PQRS payment adjustment.

Unlike eligible professionals who choose to report individually, eligible professionals choosing to participate as part of a group practice under the GPRO will need to indicate their intent to participate in PQRS as a group practice. The total burden for group practices who submit PQRS quality measures data via the GPRO web-interface will be the time and effort associated with submitting this data. To submit quality measures data for PQRS, a group

practice needs to (1) be selected to participate in the PQRS GPRO and (2) report quality measures data. With respect to the administrative duties for being selected to participate in PQRS as a group practice, we believe it takes approximately 6 hours – including 2 hours to decide to participate in PQRS as a group practice; 2 hours to self-nominate, and 2 hours to undergo the vetting process with CMS officials – for a group practice to be selected to participate in PQRS GPRO for the applicable year. Therefore, we estimate that the cost of undergoing the GPRO selection process is (\$16/hour x 6 hours) \$96.

With respect to reporting PQRS quality measures using the GPRO web-interface, the total reporting burden is the time and effort associated with the group practice submitting the quality measures data (that is, completed the data collection interface). Based on burden estimates for the PGP demonstration, which uses the same data submission methods, we estimate the burden associated with a group practice completing the data collection interface is approximately 79 hours. Therefore, we estimate that the report cost for a group practice to submit PQRS quality measures data for an applicable year is (\$40/hour x 79 hours) \$3,160.

In addition to the GPRO web interface, please note that we are finalizing a new reporting mechanism that is available to group practices comprised of 25+ eligible professionals: the certified survey vendor for CG-CAHPS measures. With respect to using a certified survey vendor, we believe there is little to no burden associated for a group practice to report the CG CAHPS survey data to CMS because the certified survey vendor will report the CG CAHPS survey questions on the group practice's behalf. Although there may be start-up costs associated with using a certified survey vendor, we believe that a group practice will not use a certified survey vendor solely for the purpose of reporting the CG CAHPS survey for the PQRS.

Therefore, we have not included the cost of using a certified survey vendor in our burden estimates.

6. Burden Estimate on PQRS Vendor Participation in CY 2014

Aside from the burden of eligible professionals and group practices participating in PQRS, we believe that entities that wish to become qualified clinical data registries will incur costs associated with participating in PQRS. However, we believe that the burden associated with participating in PQRS for these entities is very similar to the burden associated with existing qualified registries participating in PQRS.

Based on the number of registries that have self-nominated to become a qualified PQRS registry in prior program years, we estimated that approximately 50 registries will self-nominate to be considered a qualified registry for PQRS. With respect to qualified registries and qualified clinical data registries, the total burden for qualified registries and qualified clinical data registries that submit quality measures data will be the time and effort associated with submitting this data. To submit quality measures data for the 2014 PQRS reporting periods, a registry needs to (1) become qualified for the applicable year and (2) report quality measures data on behalf of its eligible professionals. With respect to administrative duties related to the qualification process, we estimate that it takes a total of 10 hours – including 1 hour to complete the self-nomination statement, 2 hours to interview with CMS, 2 hours to calculate numerators, denominators, and measure results for each measure the registry wished to report using a CMSprovided measure flow, and 5 hours to complete an XML submission – to become qualified to report quality measures data under the PQRS. Therefore, we estimate that it costs a registry approximately (\$16.00/hour x 10 hours) \$160 to become qualified to submit quality measures data on behalf of its eligible professionals.

With respect to the reporting of quality measures data, the burden associated with reporting is the time and effort associated with the registry and qualified clinical data registry calculating quality measures results from the data submitted to the registry by its eligible professionals, submitting numerator and denominator data on quality measures, and calculating these measure results. In addition to submitting numerator and denominator data on quality measures and calculating these measure results, qualified clinical data registries are required to perform additional functions, such as providing feedback to its eligible professionals at least 4 times a year and establishing a method to benchmark and, where appropriate, risk adjust its quality measure results. We believe, however, that registries and qualified clinical data registries already perform these functions for their eligible professionals irrespective of participating in PQRS. Therefore, we believe there is little to no additional burden associated with reporting quality measures data. Whether there is any additional reporting burden varies with each registry, depending on the registry's level of savvy with submitting quality measures data for PORS.

For CY 2014, we are finalizing a new PQRS option that includes a new reporting mechanism – the qualified clinical data registry. In this final rule with comment period, we set forth the requirements for a vendor to become qualified to become a qualified clinical data registry. Under the final requirements, we note that a vendor can be both a traditional qualified registry and qualified clinical data registry under the PQRS. Indeed, as we noted previously, we believe that many of the entities that will seek to become qualified clinical data registries will be similar to the existing qualified registries. In addition, the process that we are adopting for becoming a qualified clinical data registry is similar to the process for becoming a qualified

registry. Therefore, we do not believe this new reporting mechanism will impact our registry estimates.

7. Summary of Burden Estimates on Participation in the 2014 PQRS - Eligible Professionals and Vendors

TABLE 91: Estimated Costs for Reporting PQRS Quality Measures Data for Eligible Professionals

	Hours	Cases	Number of	Hourly	Cost Per	Number of	Total
			Measures	Rate	Respondent	Respondents	Cost
Individual	5.0	1	N/A	\$16	\$80	320,422	\$32,000,0
Eligible							00
Professional							
(EP):							
Preparation							
Individual EP:	0.2	6	3	\$40	\$144	230,000	\$33,120,0
Claims							00
Individual EP:	N/A	1	N/A	N/A	Minimal	40,422	N/A ¹
Registry							
Individual EP:	N/A	1	N/A	N/A	Minimal	50,000	N/A ¹
EHR							
Group Practice:	6.0	1	N/A	\$16	\$96	5,100	\$489,600
Self-Nomination							
Group Practice:	79	1	N/A	\$40	\$3,160	340	\$1,074,40
Reporting							0

¹ We believe that eligible professionals who choose to report quality measures data to PQRS using a registry, a qualified clinical data registry, an EHR, or an EHR data submission vendor are already submitting quality measures data for other purposes. Therefore, there is little to no burden associated with reporting the quality data to CMS under PQRS.

TABLE 92: Estimated Costs to Registries to Participate in PQRS

	Hours	Hourly Rate	Cost	Number of Respondents	Total Cost
Registry: Self-Nomination	10	\$16	\$160	50	\$8,000

C. The Medicare EHR Incentive Program

The Medicare EHR Incentive Program provides incentive payments to eligible professionals, eligible hospitals, and CAHs that demonstrate meaningful use of certified EHR technology. We believe any burden or impact associated with this rule's changes to the EHR Incentive Program are already

absorbed by OCN 0938-1158 and are not subject to additional OMB review under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

D. Submission of PRA-Related Comments

If you comment on these information collection and recordkeeping requirements, please submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget,

Attention: CMS Desk Officer, [CMS-1600-FC]

Fax: (202) 395-6974; or

Email: OIRA submission@omb.eop.gov.

PRA-specifc comments must be received on/by [OFR--INSERT DATE 30-DAYS AFTER THE DATE OF PUBLICATION IN THE **FEDERAL REGISTER**].

V. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We considered all comments we received by the date and time specified in the "DATES" section of this preamble, and, when we proceeded with a subsequent document, we responded to the comments in the preamble to that document.

VI. Waiver of Proposed Rulemaking and Delay in Effective Date

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposed rule. The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed, and the terms and substance of the proposed rule or a description of the subjects and issues involved. This procedure can be waived, however, if an agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued.

We utilize HCPCS codes for Medicare payment purposes. The HCPCS is a national coding system comprised of Level I (CPT) codes and Level II (HCPCS National Codes) that are intended to provide uniformity to coding procedures, services, and supplies across all types of medical providers and suppliers. Level I (CPT) codes are copyrighted by the AMA and consist of several categories, including Category I codes which are 5-digit numeric codes, and Category III codes which are temporary codes to track emerging technology, services, and procedures. The AMA issues an annual update of the CPT code set each Fall, with January 1 as the effective date for implementing the updated CPT codes. The HCPCS, including both Level I and Level II codes, is similarly updated annually on a CY basis. Annual coding changes are not available to the public until the Fall immediately preceding the annual January update of the PFS. Because of the timing of the release of these new codes, it is impracticable for us to provide prior notice and solicit comment on these codes and the RVUs assigned to them in advance of publication of the final rule that implements the PFS. Yet, it is imperative that these coding changes be accounted for and recognized timely under the PFS for payment because services represented by these codes will be provided to Medicare beneficiaries by physicians during the CY in which they become effective. Moreover, regulations implementing HIPAA (42 CFR parts 160 and 162) require that the HCPCS be used to report health care services, including services paid under the PFS. We assign interim RVUs to any new codes based on a review of the AMA RUC recommendations for valuing these services. We also assign interim RVUs to certain codes for which we did not receive specific AMA RUC recommendations, but that are components of new combined codes. We set interim RVUs for the component codes in order to conform them to the value of the combined code. Finally, we assign interim RVUs to certain codes for which we received AMA RUC recommendations for only one component (work or PE) but not both. By

reviewing these AMA RUC recommendations for the new codes, we are able to assign RVUs to services based on input from the medical community and to establish payment for them, on an interim basis, that corresponds to the relative resources associated with furnishing the services. We are also able to determine, on an interim final basis, whether the codes will be subject other payment policies. If we did not assign RVUs to new codes on an interim basis, the alternative would be to either not pay for these services during the initial CY or have each Medicare contractor establish a payment rate for these new codes. We believe both of these alternatives are contrary to the public interest, particularly since the AMA RUC process allows for an assessment of the valuation of these services by the medical community prior to our establishing payment for these codes on an interim basis. Therefore, we believe it would be contrary to the public interest to delay establishment of fee schedule payment amounts for these codes until notice and comment procedures could be completed.

For the reasons previously outlined in this section, we find good cause to waive the notice of proposed rulemaking for the interim RVUs for selected procedure codes identified in Addendum C and to establish RVUs for these codes on an interim final basis. We are providing a 60-day public comment period.

Section II.E. of this final rule with comment period discusses our review and decisions regarding the AMA RUC recommendations. Similar to the AMA RUC recommendations for new and revised codes previously discussed, due to the timing of the AMA RUC recommendations for the services identified as potentially misvalued codes, it is impracticable for CMS to provide for notice and comment regarding specific revisions prior to publication of this final rule with comment period. We believe it is in the public interest to implement the revised RVUs for the codes that were identified as misvalued, and that have been reviewed and

re-evaluated by the AMA RUC, on an interim final basis for CY 2013. The revisions of RVUs for these codes will establish a more appropriate payment that better corresponds to the relative resources associated with furnishing these services. A delay in implementing revised values for these misvalued codes would not only perpetuate the known misvaluation for these services, it would also perpetuate a distortion in the payment for other services under the PFS.

Implementing the changes on an interim basis allows for a more equitable distribution of payments across all PFS services. We believe a delay in implementation of these revisions would be contrary to the public interest, particularly since the AMA RUC process allows for an assessment of the valuation of these services by the medical community prior to the AMA RUC's recommendation to CMS. For the reasons previously described, we find good cause to waive notice and comment procedures with respect to the misvalued codes and to revise RVUs for these codes on an interim final basis. We are providing a 60-day public comment period.

In the absence of an appropriation for CY 2014 or a Continuing Resolution, there was a lapse in funding, which lasted from October 1 through October 16, 2013, when only excepted operations continued. This largely excluded work on this final rule with comment period.

Accordingly, most of the work on this final rule with comment period was not completed in accordance with our usual schedule for final CY payment rules, which aims for an issuance date of November 1 followed by an effective date of January 1 to ensure that the policies are effective at the start of the calendar year to which they apply.

We ordinarily provide a 60-day delay in the effective date of final rules after the date they are issued. The 60-day delay in effective date can be waived, however, if the agency finds for good cause that the delay is impracticable, unnecessary, or contrary to the public interest, and the agency incorporates a statement of the findings and its reasons in the rule issued. We believe it

would be contrary to the public interest to delay the effective date of the MPFS portions of this final rule with comment period. In accordance with section 1848(b)(1) of the statute, the MPFS is a calendar-year payment system. We typically issue the final rule by November 1 of each year to comply with section 1848(b)(1) of the statute and to ensure that the payment policies for the system are effective on January 1, the first day of the calendar year to which the policies are intended to apply. If the effective date of this final rule with comment period is delayed by 60 days, the MPFS for CY 2014 adopted in this final rule with comment period will not be effective as of the beginning of the payment year. Section 1848(d) of the Act requires application of an update, calculated using the SGR methodology, to the CF that is used to calculate payments under the MPFS. The statutory update is required to be applied to the CF for the previous year in order to calculate the CF for the succeeding year. As such, it is necessary that the statutory update to the CF take effect as of the beginning of the calendar year in order to adjust MPFS payments as prescribed by statute. In addition, in this final rule with comment period, we review and revise values for specific services, and adopt or revise other policies that relate to the MPFS for CY 2014 or future years. Section 1848(c)(2)(B)(ii)(II) of the Act requires that adjustments to relative values under the MPFS be made in a budget neutral manner. We believe that, in order to preserve budget neutrality as required by statute and to promote an orderly transition to a new payment year, it is in the public interest for all of these MPFS policies to take effect in conjunction with the statutory update to the CF for CY 2014, and we find that it would be contrary to the public interest to do otherwise. We are finalizing the MPFS in this CY 2014 final rule with comment period and, in order to adhere to the statutory requirements that an adjusted CF apply to services furnished on or after January 1, 2014, and that budget neutrality be maintained, this final rule must be effective on that date.

Additionally, we believe it would be contrary to the public interest to delay the effective date of the PORS, value-based payment modifier, EHR incentive program, and Medicare Shared Savings provisions of this final rule with comment period. PORS incentives for 2014 and PORS payment adjustments for 2016, as authorized under subsections (m) and (a) of section 1848, will be based, in part, on the policies finalized in this final rule, including the requirements for reporting quality data beginning January 1, 2014. The CY 2016 value-based payment modifier, as authorized under section 1848(p), will be determined according to final policies adopted in this rule and using a performance period that begins on January 1, 2014. We are also finalizing policies in this rule that pertain to the reporting of clinical quality measures for the EHR Incentive Program during CY 2014, which will be used to determine incentive payments and payments adjustments under sections 1848(o) and (a)(7), respectively. If the effective date of this final rule with comment period is delayed by 60 days, the PORS policies adopted in this final rule will not be effective until after January 1, 2014. This would be contrary to the public's interest in ensuring that eligible professionals have the full benefit of reporting during CY 2014, receive appropriate incentive payments in a timely manner, and that their physician fee schedule payments in 2016 are properly adjusted to reflect their reporting on quality measure data in 2014. For the same reasons, we believe it would be contrary to the public interest to delay by 60 days the effective date of the policies related to the CY 2016 value-based payment modifier and the EHR Incentive Program. In addition, under the authority provided by section 1899(b)(3)(D) of the Act, certain PQRS requirements regarding reporting for purposes of incentive payments and the payment adjustment under section 1848(a)(8) were incorporated in the Medicare Shared Savings Program. Accordingly, for the same reasons described above, it would also be contrary

to the public interest to delay the effective date of the provisions regarding PQRS reporting under the Medicare Shared Savings Program beyond January 1, 2014.

Therefore, we find good cause to waive the 60-day delay in the effective date for this final rule with comment period as explained above. We note that our waiver of the delayed effective date only applies to the provisions noted above that are being adopted in this final rule with comment period. The delayed effective date is not waived for other provisions of this final rule with comment period, and those policies will be effective on **[OFR--INSERT date that is 60 days after OFR display]**.

VII. Regulatory Impact Analysis

A. Statement of Need

This final rule with comment period is necessary to make payment and policy changes under the Medicare PFS and to make required statutory changes under the Affordable Care Act (Pub. L. 111–148), the Middle Class Tax Relief and Job Creation Act of 2012 (Pub. L. 112-96), the American Taxpayer Relief Act (ATRA) of 2013 (Pub. L. 112-240), and other statutory changes. This final rule with comment period also is necessary to make changes to other Part B related policies.

B. Overall Impact

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (February 2, 2013), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). We estimate, as discussed below in this section, that the PFS provisions included in this final rule with comment period will redistribute more than \$100 million in 1 year. Therefore, we estimate that this rulemaking is "economically significant" as measured by the \$100 million

threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we have prepared a RIA that, to the best of our ability, presents the costs and benefits of the rulemaking. The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than \$7.0 million in any 1 year (for details see the SBA's website at http://www.sba.gov/content/small-business-size-standards# (refer to the 620000 series)). Individuals and states are not included in the definition of a small entity.

The RFA requires that we analyze regulatory options for small businesses and other entities. We prepare a regulatory flexibility analysis unless we certify that a rule would not have a significant economic impact on a substantial number of small entities. The analysis must include a justification concerning the reason action is being taken, the kinds and number of small entities the rule affects, and an explanation of any meaningful options that achieve the objectives with less significant adverse economic impact on the small entities.

For purposes of the RFA, physicians, NPPs, and suppliers are considered small businesses if they generate revenues of \$10 million or less based on SBA size standards.

Approximately 95 percent of providers and suppliers are considered to be small entities. There are over 1 million physicians, other practitioners, and medical suppliers that receive Medicare payment under the PFS. Because many of the affected entities are small entities, the analysis and discussion provided in this section as well as elsewhere in this final rule with comment period is intended to comply with the RFA requirements.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a

significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this final rule with comment period would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits on state, local, or tribal governments or on the private sector before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2013, that threshold is approximately \$141 million. This final rule with comment period will impose no mandates on state, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule with comment period (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. Since this regulation does not impose any costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

We have prepared the following analysis, which together with the information provided in the rest of this preamble, meets all assessment requirements. The analysis explains the rationale for and purposes of this final rule with comment period; details the costs and benefits of the rule; analyzes alternatives; and presents the measures we would use to minimize the burden on small entities. As indicated elsewhere in this final rule with comment period, we are

implementing a variety of changes to our regulations, payments, or payment policies to ensure that our payment systems reflect changes in medical practice and the relative value of services, and to implement statutory provisions. We provide information for each of the policy changes in the relevant sections of this final rule with comment period. We are unaware of any relevant federal rules that duplicate, overlap, or conflict with this final rule with comment period. The relevant sections of this final rule with comment period contain a description of significant alternatives if applicable.

C. Relative Value Unit (RVU) Impacts

1. Resource-Based Work, PE, and Malpractice RVUs

Section 1848(c)(2)(B)(ii)(II) of the Act requires that increases or decreases in RVUs may not cause the amount of expenditures for the year to differ by more than \$20 million from what expenditures would have been in the absence of these changes. If this threshold is exceeded, we make adjustments to preserve budget neutrality.

Our estimates of changes in Medicare revenues for PFS services compare payment rates for CY 2013 with payment rates for CY 2014 using CY 2012 Medicare utilization as the basis for the comparison. The payment impacts reflect averages for each specialty based on Medicare utilization. The payment impact for an individual physician could vary from the average and would depend on the mix of services the physician furnishes. The average change in total revenues would be less than the impact displayed here because physicians furnish services to both Medicare and non-Medicare patients and specialties may receive substantial Medicare revenues for services that are not paid under the PFS. For instance, independent laboratories receive approximately 83 percent of their Medicare revenues from clinical laboratory services that are not paid under the PFS.

We note that these impacts do not include the effect of the January 2014 conversion factor changes under current law. The annual update to the PFS conversion factor is calculated based on a statutory formula that measures actual versus allowed or "target" expenditures, and applies a sustainable growth rate (SGR) calculation intended to control growth in aggregate Medicare expenditures for physicians' services. This update methodology is typically referred to as the "SGR" methodology, although the SGR is only one component of the formula. Medicare PFS payments for services are not withheld if the percentage increase in actual expenditures exceeds the SGR. Rather, the PFS update, as specified in section 1848(d)(4) of the Act, is adjusted to eventually bring actual expenditures back in line with targets. If actual expenditures exceed allowed expenditures, the update is reduced. If actual expenditures are less than allowed expenditures, the update is increased. By law, we are required to apply these updates in accordance with sections 1848(d) and (f) of the Act, and any negative updates can only be averted by an Act of the Congress. Although the Congress has provided temporary relief from negative updates for every year since 2003, a long-term solution is critical. We are committed to working with the Congress to reform Medicare physician payments to provide predictable payments that incentivize quality and efficiency in a fiscally responsible way. We provide our most recent estimate of the SGR and physician update for CY 2014 in section II.G. of this final rule with comment period.

Table 93 shows the payment impact by Medicare specialty. To the extent that there are year-to-year changes in the volume and mix of services provided by physicians, the actual impact on total Medicare revenues will be different from those shown in Table 93 (CY 2014 PFS Final Rule with Comment Period Estimated Impact on Total Allowed Charges by Specialty).

The following is an explanation of the information represented in Table 93:

• <u>Column A (Specialty)</u>: The Medicare specialty code as reflected in our physician/supplier enrollment files.

- Column B (Allowed Charges): The aggregate estimated PFS allowed charges for the specialty based on CY 2012 utilization and CY 2013 rates. That is, allowed charges are the PFS amounts for covered services and include coinsurance and deductibles (which are the financial responsibility of the beneficiary). These amounts have been summed across all services furnished by physicians, practitioners, and suppliers within a specialty to arrive at the total allowed charges for the specialty.
- Column C (Impact of Work and Malpractice (MP) RVU Changes): This column shows the estimated CY 2014 impact on total allowed charges of the changes in the work and malpractice RVUs, including the impact of changes due to new, revised, and misvalued codes.
- Column D (Impact of PE RVU Changes): This column shows the estimated CY 2014 impact on total allowed charges of the changes in the PE RVUs, including the impact of changes due to new, revised, and misvalued codes, the statutory change to the equipment utilization rate from 75 percent to 90 percent for expensive diagnostic imaging equipment, the implementation of the ultrasound recommendation to replace expensive ultrasound rooms with less expense portable ultrasound units, and other miscellaneous and minor provisions.
- Column E (Impact of Adjusting the RVUs to Match the Revised MEI Weights): This column shows the estimated CY 2014 combined impact on total allowed charges of the changes in the RVUs and conversion factor adjustment resulting from adjusting the RVUs to match the revised MEI weights.
- Column F (Cumulative Impact): This column shows the estimated CY 2014 combined impact on total allowed charges of all the changes in the previous columns.

TABLE 93: CY 2014 PFS Final Rule with Comment Period Estimated Impact Table: Impacts of Work, Practice Expense, and Malpractice RVUs, and the MEI Adjustment*

Impacts of Work, Practice Expense, a	mu Maipr	actice KV	Js, and the		istinent"	
		Impact	of RVU	(E)		
	(F)	Cha	nges	Impact of		
	(B)	(C)		Adjusting	(F)	
(A)	A 11 1	Impact	(D)	the RVUs	(F)	
Specialty	Allowed	of Work	Impact	to Match	Combined	
	Charges	and MP	of PE	the	Impact	
	(mil)	RVU	RVU	Revised		
		Changes	Changes	MEI Weights		
TOTAL	\$87,552	0%	0%	0%	0%	
01-ALLERGY/IMMUNOLOGY	\$214	0%	0%	-3%	-3%	
02-ANESTHESIOLOGY	\$1,871	0%	0%	1%	1%	
03-CARDIAC SURGERY	\$357	0%	0%	2%	2%	
04-CARDIOLOGY	\$6,461	0%	2%	-1%	1%	
05-COLON AND RECTAL SURGERY	\$159	0%	0%	0%	0%	
06-CRITICAL CARE	\$276	0%	0%	2%	2%	
07-DERMATOLOGY	\$3,123	-1%	1%	-2%	-2%	
08-EMERGENCY MEDICINE	\$2,946	0%	0%	2%	2%	
09-ENDOCRINOLOGY	\$449	0%	0%	0%	0%	
10-FAMILY PRACTICE	\$6,402	0%	0%	0%	0%	
11-GASTROENTEROLOGY	\$1,909	-1%	-1%	0%	-2%	
12-GENERAL PRACTICE	\$536	0%	0%	0%	0%	
13-GENERAL SURGERY	\$2,254	0%	0%	0%	0%	
14-GERIATRICS	\$235	0%	0%	1%	1%	
15-HAND SURGERY	\$151	0%	0%	-1%	-1%	
16-HEMATOLOGY/ONCOLOGY	\$1,896	0%	0%	-2%	-2%	
17-INFECTIOUS DISEASE	\$639	0%	0%	2%	2%	
18-INTERNAL MEDICINE	\$11,503	0%	0%	1%	1%	
19-INTERVENTIONAL PAIN MGMT	\$644	-1%	-2%	-1%	-4%	
20-INTERVENTIONAL RADIOLOGY	\$221	-1%	0%	-1%	-2%	
21-MULTISPECIALTY CLINIC/OTHER	\$80	0%	-1%	1%	0%	
PHY						
22-NEPHROLOGY	\$2,134	0%	0%	1%	1%	
23-NEUROLOGY	\$1,509	0%	-1%	0%	-1%	
24-NEUROSURGERY	\$718	0%	0%	0%	0%	
25-NUCLEAR MEDICINE	\$51	0%	0%	0%	0%	
27-OBSTETRICS/GYNECOLOGY	\$693	0%	2%	-1%	1%	
28-OPHTHALMOLOGY	\$5,609	0%	0%	0%	0%	
29-ORTHOPEDIC SURGERY	\$3,702	-1%	-1%	0%	-2%	

	(B)	Impact Char		(E) Impact of		
(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work and MP RVU	(D) Impact of PE RVU Changes	Adjusting the RVUs to Match the Revised MEI	(F) Combined Impact	
		Changes	Changes	Weights		
30-OTOLARNGOLOGY	\$1,133	0%	-1%	-1%	-2%	
31-PATHOLOGY	\$1,141	-4%	-2%	0%	-6%	
32-PEDIATRICS	\$64	0%	0%	0%	0%	
33-PHYSICAL MEDICINE	\$1,007	0%	-1%	0%	-1%	
34-PLASTIC SURGERY	\$372	0%	0%	0%	0%	
35-PSYCHIATRY	\$1,181	4%	1%	1%	6%	
36-PULMONARY DISEASE	\$1,783	0%	0%	1%	1%	
37-RADIATION ONCOLOGY	\$1,788	0%	3%	-2%	1%	
38-RADIOLOGY	\$4,655	0%	-2%	0%	-2%	
39-RHEUMATOLOGY	\$553	0%	-2%	-2%	-4%	
40-THORACIC SURGERY	\$335	0%	0%	1%	1%	
41-UROLOGY	\$1,864	0%	-1%	0%	-1%	
42-VASCULAR SURGERY	\$931	0%	-1%	-1%	-2%	
43-AUDIOLOGIST	\$57	0%	1%	-1%	0%	
44-CHIROPRACTOR	\$729	5%	6%	1%	12%	
45-CLINICAL PSYCHOLOGIST	\$587	6%	-1%	3%	8%	
46-CLINICAL SOCIAL WORKER	\$414	6%	-2%	4%	8%	
47-DIAGNOSTIC TESTING FACILITY	\$790	0%	-6%	-5%	-11%	
48-INDEPENDENT LABORATORY	\$818	-2%	0%	-3%	-5%	
49-NURSE ANES / ANES ASST	\$1,061	0%	0%	3%	3%	
50-NURSE PRACTITIONER	\$1,954	0%	0%	1%	1%	
51-OPTOMETRY	\$1,116	0%	0%	-1%	-1%	
52-ORAL/MAXILLOFACIAL SURGERY	\$45	0%	1%	-2%	-1%	
53-PHYSICAL/OCCUPATIONAL THERAPY	\$2,818	0%	1%	-1%	0%	
54-PHYSICIAN ASSISTANT	\$1,414	0%	0%	0%	0%	
55-PODIATRY	\$1,998	0%	0%	-1%	-1%	
56-PORTABLE X-RAY SUPPLIER	\$113	0%	2%	-4%	-2%	
57-RADIATION THERAPY CENTERS	\$63	0%	5%	-6%	-1%	
98-OTHER	\$25	0%	0%	1%	1%	

*Table 93 shows only the payment impact on PFS services. These impacts use a constant conversion factor and thus do not include the effects of the January 2014 conversion factor change required under current law.

2. CY 2014 PFS Impact Discussion

a. Changes in RVUs

The most widespread specialty impacts of the RVU changes are generally related to the following major factors. The first factor is our rescaling of the RVUs to match the weights assigned to work, PE and MP in the revised MEI, as discussed in section II.B. of this final rule with comment period. A conversion factor (CF) adjustment is also made to assure budget neutrality for this adjustment in RVUs. The second factor involves service-level changes to RVUs for new, revised, and misvalued services. In addition, a number of other changes contribute to the impacts shown in Table 93. Other factors include a statutory change that requires us to use a 90 percent equipment utilization rate rather than the previously used 75 percent for expensive diagnostic imaging equipment as discussed in section II.A.2.f. of this final rule with comment period, updates to direct practice expense inputs for ultrasound services, as discussed in section II.A.5. of this final rule with comment period and adjustments to time for some services, as discussed in section II.B.3.c. of this final rule with comment period.

b. Combined Impact

Column F of Table 93 displays the estimated CY 2014 combined impact on total allowed charges by specialty of all the RVU changes. These impacts range from an increase of 12 percent for chiropractors to a decrease of 10 percent for diagnostic testing facilities. Again, these impacts are estimated prior to the application of the negative CY 2014 CF update applicable under the Act.

Table 94 (Impact of Final rule with comment period on CY 2014 Payment for Selected Procedures) shows the estimated impact on total payments for selected high volume procedures

of all of the changes discussed previously. We have included CY 2014 payment rates with and without the effect of the CY 2014 negative PFS CF update for comparison purposes. We selected these procedures from among the most commonly furnished by a broad spectrum of physician specialties. The change in both facility rates and the nonfacility rates are shown. For an explanation of facility and nonfacility PE, we refer readers to Addendum A of this final rule with comment period.

TABLE 94: Impact of Final Rule with Comment Period on CY 2014 Payment for Selected Procedures*

		•			Non-Facility							
CPT/ HCPCS ¹	MOD	Short Descriptor	$\mathrm{CY}\ 2013^2$	CY 2014 ³ (pre update)	% Change (pre update)	CY 2014 ⁴ (post update)	% Change (post update)	$CY 2013^2$	CY 2014 ³ (pre update)	% Change (pre update)	CY 2014 ⁴ (post update)	% Change (post update)
11721		Debride nail 6 or more	\$24.50	\$25.30	3%	\$18.59	-24%	\$44.91	\$44.89	0%	\$33.00	-27%
17000		Destruct premalg lesion	\$57.16	\$53.09	-7%	\$39.02	-32%	\$83.36	\$74.82	-10%	\$54.99	-34%
27130		Total hip arthroplasty	\$1,454.48	\$1,393.78	-4%	\$1,024.43	-30%	NA	NA	NA	NA	NA
27244		Treat thigh fracture	\$1,242.18	\$1,260.53	1%	\$926.49	-25%	NA	NA	NA	NA	NA
27447		Total knee arthroplasty	\$1,552.81	\$1,393.06	-10%	\$1,023.91	-34%	NA	NA	NA	NA	NA
33533		Cabg arterial single	\$1,906.31	\$1,958.13	3%	\$1,439.23	-25%	NA	NA	NA	NA	NA
35301		Rechanneling of artery	\$1,096.22	\$1,201.38	10%	\$883.02	-19%	NA	NA	NA	NA	NA
43239		Egd biopsy single/multiple	\$174.54	\$152.13	-13%	\$111.82	-36%	\$359.28	\$404.02	12%	\$296.96	-17%
66821		After cataract laser surgery	\$325.26	\$323.50	-1%	\$237.78	-27%	\$344.99	\$341.32	-1%	\$250.87	-27%
66984		Cataract surg w/iol 1 stage	\$667.87	\$671.59	1%	\$493.62	-26%	NA	NA	NA	NA	NA
67210		Treatment of retinal lesion	\$520.55	\$521.95	0%	\$383.64	-26%	\$538.92	\$539.41	0%	\$396.47	-26%
71010		Chest x-ray 1 view frontal	NA	NA	NA	NA	NA	\$23.82	\$23.87	0%	\$17.55	-26%
71010	26	Chest x-ray 1 view frontal	\$8.85	\$9.26	5%	\$6.81	-23%	\$8.85	\$9.26	5%	\$6.81	-23%
77056		Mammogram both breasts	NA	NA	NA	NA	NA	\$114.66	\$115.44	1%	\$84.85	-26%
77056	26	Mammogram both breasts	\$42.19	\$44.18	5%	\$32.47	-23%	\$42.19	\$44.18	5%	\$32.47	-23%
77057		Mammogram screening	NA	NA	NA	NA	NA	\$81.66	\$82.30	1%	\$60.49	-26%
77057	26	Mammogram screening	\$34.02	\$35.63	5%	\$26.19	-23%	\$34.02	\$35.63	5%	\$26.19	-23%
77427		Radiation tx management	\$178.28	\$185.62	4%	\$136.43	-23%	\$178.28	\$185.62	4%	\$136.43	-23%
88305	26	Tissue exam by pathologist	\$36.74	\$38.12	4%	\$28.02	-24%	\$36.74	\$38.12	4%	\$28.02	-24%
90935		Hemodialysis one	\$71.11	\$73.04	3%	\$53.68	-25%	NA	NA	NA	NA	NA
92012		Eye exam establish patient	\$53.08	\$54.51	3%	\$40.07	-25%	\$87.44	\$86.58	-1%	\$63.63	-27%
92014		Eye exam&tx estab pt	\$80.29	\$82.30	2%	\$60.49	-25%	\$126.23	\$125.41	-1%	\$92.18	-27%
93000		Electrocardiogram complete	NA	NA	NA	NA	NA	\$18.37	\$16.75	-9%	\$12.31	-33%
93010		Electrocardiogram report	\$8.17	\$8.55	5%	\$6.28	-23%	\$8.17	\$8.55	5%	\$6.28	-23%
93015		Cardiovascular stress test	NA	NA	NA	NA	NA	\$79.61	\$75.53	-5%	\$55.52	-30%

		Facility						Non-Facility				
MOD	Short Descriptor	$\mathrm{CY}\ 2013^2$	CY 2014 ³ (pre update)	% Change (pre update)	CY 2014 ⁴ (post update)	% Change (post update)	$CY 2013^2$	CY 2014 ³ (pre update)	% Change (pre update)	CY 2014 ⁴ (post update)	% Change (post update)	
26	Tte w/o doppler complete	\$44.23	\$45.60	3%	\$33.52	-24%	\$44.23	\$45.60	3%	\$33.52	-24%	
26	L hrt artery/ventricle angio	\$315.73	\$326.00	3%	\$239.61	-24%	\$315.73	\$326.00	3%	\$239.61	-24%	
	Chiropract manj 3-4 regions	\$30.62	\$35.27	15%	\$25.92	-15%	\$36.40	\$41.33	14%	\$30.38	-17%	
	Office/outpatient visit new	\$75.19	\$76.96	2%	\$56.56	-25%	\$108.19	\$107.95	0%	\$79.35	-27%	
	Office/outpatient visit est	\$49.67	\$51.30	3%	\$37.71	-24%	\$72.81	\$72.68	0%	\$53.42	-27%	
	Office/outpatient visit est	\$76.55	\$78.74	3%	\$57.87	-24%	\$106.83	\$107.24	0%	\$78.82	-26%	
	Initial hospital care	\$134.73	\$138.24	3%	\$101.60	-25%	NA	NA	NA	NA	NA	
	Initial hospital care	\$198.01	\$203.44	3%	\$149.53	-24%	NA	NA	NA	NA	NA	
	Subsequent hospital care	\$38.11	\$39.19	3%	\$28.81	-24%	NA	NA	NA	NA	NA	
	Subsequent hospital care	\$70.09	\$71.97	3%	\$52.90	-25%	NA	NA	NA	NA	NA	
	Subsequent hospital care	\$101.05	\$104.03	3%	\$76.47	-24%	NA	NA	NA	NA	NA	
	Observ/hosp same date	\$212.30	\$218.40	3%	\$160.53	-24%	NA	NA	NA	NA	NA	
	Hospital discharge day	\$104.79	\$106.88	2%	\$78.56	-25%	NA	NA	NA	NA	NA	
	Emergency dept visit	\$59.88	\$61.64	3%	\$45.30	-24%	NA	NA	NA	NA	NA	
	Emergency dept visit	\$114.66	\$117.93	3%	\$86.68	-24%	NA	NA	NA	NA	NA	
	Critical care first hour	\$217.75	\$223.75	3%	\$164.45	-24%	\$272.18	\$273.62	1%	\$201.11	-26%	
	Critical care addl 30 min	\$109.55	\$112.23	2%	\$82.49	-25%	\$120.78	\$122.92	2%	\$90.34	-25%	
	Home visit est patient	NA	NA	NA	NA	NA	\$82.34	\$84.08	2%	\$61.80	-25%	
	Home visit est patient	NA	NA	NA	NA	NA	\$173.52	\$177.78	2%	\$130.67	-25%	
	Immunization admin	NA	NA	NA	NA	NA	\$25.86	\$24.94	-4%	\$18.33	-29%	
	26	26 Tte w/o doppler complete 26 L hrt artery/ventricle angio Chiropract manj 3-4 regions Office/outpatient visit new Office/outpatient visit est Office/outpatient visit est Initial hospital care Initial hospital care Subsequent hospital care Subsequent hospital care Subsequent hospital care Observ/hosp same date Hospital discharge day Emergency dept visit Emergency dept visit Critical care addl 30 min Home visit est patient Home visit est patient	Tte w/o doppler complete Chiropract manj 3-4 regions Salo.62 Office/outpatient visit new Coffice/outpatient visit est Coffice/outpatient visit est Salo.62 Office/outpatient visit est Salo.62 Office/outpatient visit est Salo.62 Office/outpatient visit est Salo.62 Office/outpatient visit est Salo.62 Salo.62	26 Tte w/o doppler complete \$44.23 \$45.60 26 L hrt artery/ventricle angio \$315.73 \$326.00 Chiropract manj 3-4 regions \$30.62 \$35.27 Office/outpatient visit new \$75.19 \$76.96 Office/outpatient visit est \$49.67 \$51.30 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¹ CPT codes and descriptions are copyright 2013 American Medical Association. All Rights Reserved. Applicable FARS/DFARS apply.

² Payments based on the 2013 conversion factor of 34.0230.

³ Payments based on the 2013 conversion factor of 34.0230, adjusted to 35.6446 to include the budget neutrality adjustment.

⁴ Payments based on the estimated 2014 conversion factor of 27.2006.

D. Effect of Changes to Medicare Telehealth Services Under the PFS

As discussed in section II.E.3. of this final rule with comment period, we are finalizing our policy to refine our definition of rural as it applies to HPSAs eligible for telehealth services as well as add transitional care management services to the list of Medicare telehealth services. Although we expect these changes to increase access to care in rural areas, based on recent utilization of current Medicare telehealth services, including services similar to transitional care management, we estimate no significant impact on PFS expenditures from the additions.

E. Geographic Practice Cost Indices (GPCIs)

Based upon statutory requirements we are updating the GPCIs for each Medicare payment locality. The GPCIs incorporate the use of updated data and cost share weights as discussed in II.E. The Act requires that updated GPCIs be phased in over 2 years. Addendum D shows the estimated effects of the revised GPCIs on area GAFs for the transition year (CY 2014) and the fully implemented year (CY 2015). The GAFs reflect the use of the updated underlying GPCI data, and the revised cost share weights. The GAFs are a weighted composite of each area's work, PE and malpractice expense GPCIs using the national GPCI cost share weights. Although we do not actually use the GAFs in computing the fee schedule payment for a specific service, they are useful in comparing overall areas costs and payments. The actual geographic adjustment to payment for any actual service will be different from the GAF to the extent that the proportions of work, PE and malpractice expense RVUs for the service differ from those of the GAF.

The most significant changes occur in 22 payment localities where the fully implemented (CY 2015) GAF moves up by more than 1 percent (11 payment localities) or down by more than 2 percent (11 payment localities). The impacts on the GPCIs are primarily attributed to the

expiration of the 1.000 work GPCI floor. The use of updated underlying GPCI data and cost share weights has a minimal impact on locality GAFs. The total impact of the GPCI revisions is shown in the 2015 GPCI values of Addendum E.

We note that the CY 2014 physician work GPCIs and summarized geographic adjustment factors (GAFs) published in Addenda D and E reflect the elimination of the 1.0 work GPCI floor provided in section 1848 (e)(1)(E) of the Act, which is set to expire prior to the implementation of the CY 2014 PFS.

F. Other Provisions of the Final Rule with Comment Period Regulation

1. Rebasing and Revising Medicare Economic Index

We estimate that there is no impact of the changes to the MEI for CY 2014.

2. Coverage of Items and Services furnished in FDA-Approved Investigational Device Exemption (IDE) Clinical Trials

We are finalizing our proposal of a transparent centralized review process that would be more efficient by reducing the burden for stakeholders. Once the IDE coverage process is centralized, there will be a single entity making the IDE coverage decision. This also eliminates duplicative reviews by Medicare local contractors and the numerous applications sent to contractors by stakeholders requesting IDE coverage. We believe that a centralized review process will not significantly reduce the number of IDE devices currently covered.

3. Ultrasound Screening for Abdominal Aortic Aneurysms

As discussed in section III.B. of this final rule with comment period, section 1861(s)(2)(AA) of the Act, with implementing regulations at §410.19, authorizes Medicare coverage of ultrasound screening for abdominal aortic aneurysms ("AAA screening"). We are finalizing our proposal to modify §410.19 to allow coverage of one-time AAA screening without

receiving a referral as part of the IPPE, for beneficiaries that meet certain other eligibility criteria (a family history of AAA or, for men aged 65-75, a history of smoking). Approximately 45 percent of men aged 65-75 have a history of smoking. It is unknown how many individuals have a family history of AAA or how many beneficiaries will avail themselves of this benefit. Therefore, the impact of this change is unknown for CY 2014.

4. Modification to Medicare Coverage of Colorectal Cancer Screening

As discussed in section III.C. of this final rule with comment period, sections 1861(s)(2)(R) and 1861(pp)(1) of the Act, and implementing regulations at 42 CFR 410.37 authorize Medicare coverage of screening FOBT. We are finalizing our proposal to modify §410.37(b) to allow attending physicians, physician assistants, nurse practitioners, and clinical nurse specialists to furnish orders for screening FOBTs. Although there may be an increase in utilization, particularly in rural areas, it is unknown how many individuals will avail themselves of this benefit. Therefore, the impact of this change is unknown for CY 2014.

5. Ambulance Fee Schedule

As discussed in section III.D. of this final rule with comment period, section 604(a) through (c) of the ATRA require the extension of certain add-on payments for ground ambulance services and the extension of certain rural area designations for purposes of air ambulance payment. In addition, as discussed in section III.D. of this final rule with comment period, section 637 of the ATRA (which added section 1834(1)(15) of the Act) specifies that the fee schedule amount otherwise applicable under the preceding provisions of section 1834(1) of the Act shall be reduced by 10 percent for ambulance services furnished on or after October 1, 2013, consisting of non-emergency basic life support (BLS) services involving transport of an individual with end-stage renal disease for renal dialysis services (as described in section

1881(b)(14)(B) of the Act) furnished other than on an emergency basis by a provider of services or a renal dialysis facility. The ambulance extender provisions and the mandated 10 percent rate decrease discussed above are enacted through legislation that is self-implementing. We are finalizing our proposal to amend the regulation text at §414.610 only to conform the regulations to these self-implementing statutory requirements. As a result, we are not making any policy proposals associated with these legislative provisions and there is no associated regulatory impact

6. Clinical Laboratory Fee Schedule

We are finalizing our proposal to add language to the Code of Federal Regulations to codify authority provided by statute and to establish a process under which we will systematically reexamine the payment amounts established under the CLFS to determine if changes in technology for the delivery of that service warrant an adjustment to the payment amount. We are also finalizing our proposal of a definition for the term technological changes. Adjustments made under the new process could both increase fee schedule amounts and provide for reductions in existing amounts. We cannot estimate a net impact at this time.

 Liability for Overpayments to or on Behalf of Individuals including Payments to Providers or Other Persons

As discussed in section III.F. of this final rule with comment period, we are finalizing the regulation as proposed and changing the timeframe for the "without fault" presumptions from 3 years to 5 years. As a result, there would be an estimated savings of \$0.5 billion over 10 years.

8. Physician Compare Web Site

There will be no impact for the Physician Compare website because we are not collecting any information for the Physician Compare website.

9. Physician Payment, Efficiency, and Quality Improvements – Physician Quality Reporting System (PQRS)

In the CY 2013 PFS final rule with comment period, we provided estimates related to the impact of the requirements we finalized for the PQRS for 2014. Since we are making additional proposals for 2014, this section modifies the impact statement provided for 2014 in the CY 2013 PFS final rule with comment period. Please note that we will base our estimates on information found in the 2011 Physician Quality Reporting System and eRx Reporting Experience and Trends (hereinafter "the PQRS Reporting Experience"). This report contains the latest data we have gathered on PQRS participation. The PQRS Reporting Experience is available at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/index.html?redirect=/PQRS/. According to the 2011 Reporting Experience Report, over 1 million professionals were eligible to participate in the PQRS. A total of \$261,733,236 in PQRS incentives was paid by CMS for the 2011 program year, which encompassed 26,515 practices that included 266,521 eligible professionals (or approximately 27 percent of the professionals eligible to participate). The average incentive earned for PQRS in 2011 per each individually-participating eligible professional was \$1,059.

As we noted in our impact statement last year, we expect that, due to the implementation of payment adjustments beginning in 2015, participation in the PQRS would rise incrementally to approximately 300,000 eligible professionals and 400,000 eligible professionals in 2013 and 2014, respectively. We believe our estimate of 400,000 eligible professionals participating in PQRS in 2014 remains accurate.

With respect to the estimate amount of incentives earned, for 2014, eligible professionals can earn a 0.5 percent incentive (that is, a bonus payment equal to 0.5 percent of the total

allowed Part B charges for covered professional services under the PFS furnished by the eligible professional during the reporting period) for satisfactory reporting. Based on information drawn from the 2011 Reporting Experience and our participation estimate, we believe that, out of the 400,000 eligible professionals we expect to participate in the PQRS in 2014, the PQRS will distribute 2014 incentives to approximately (27 percent of 1 million eligible professionals) 270,000 eligible professionals. At \$1,059 per eligible professional, the PQRS would distribute approximately \$286 million in incentive payments in 2014. We believe these incentive payments will help offset the cost eligible professionals may undertake for participating in the PQRS for the applicable year.

We note that the total burden associated with participating in the PQRS is the time and effort associated with indicating intent to participate in the PQRS, if applicable, and submitting PQRS quality measures data. When establishing these burden estimates, we assume the following:

- For an eligible professional or group practice using the claims, registry, or EHR-based reporting mechanisms, we assume that the eligible professional or group practice would attempt to report PQRS quality measures data with the intention of earning the 2014 PQRS incentive, not simply to avoid the 2016 PQRS payment adjustment. Therefore, an eligible professionals or group practice would report on 9 measures.
- With respect to labor costs, we believe that a billing clerk will handle the administrative duties associated with participating, while a computer analyst will handle duties related to reporting PQRS quality measures. According to the Bureau of Labor Statistics, the mean hourly wage for a billing clerk is approximately \$16/hour whereas the mean hourly wage for a computer analyst is approximately \$40/hour.

For an eligible professional who wishes to participate in the PQRS as an individual, the eligible professional need not indicate his/her intent to participate. The eligible professional may simply begin reporting quality measures data. Therefore, these burden estimates for individual eligible professionals participating in the PQRS are based on the reporting mechanism the individual eligible professional chooses. However, we believe a new eligible professional or group practice would spend 5 hours—which includes 2 hours to review the PQRS measures list, review the various reporting options, and select a reporting option and measures on which to report and 3 hours to review the measure specifications and develop a mechanism for incorporating reporting of the selected measures into their office work flows. Therefore, we believe that the initial administrative costs associated with participating in the PQRS would be approximately \$80 (\$16/hour x 5 hours).

With respect to an eligible professional who participates in the PQRS via claims, the eligible professional must gather the required information, select the appropriate quality data codes (QDCs), and include the appropriate QDCs on the claims they submit for payment. The PQRS collects QDCs as additional (optional) line items on the existing HIPAA transaction 837-P and/or CMS Form 1500 (OCN: 0938-0999). Based on our experience with Physician Voluntary Reporting Program (PVRP), we continue to estimate that the time needed to perform all the steps necessary to report each measure via claims will range from 0.25 minutes to 12 minutes, depending on the complexity of the measure. Therefore, the time spent reporting 9 measures would range from 2.25 minutes to 108 minutes. Using an average labor cost of \$40/hour, we estimate that time cost of reporting for an eligible professional via claims would range from \$1.50 (2.25 minutes or 0.0375 hours x \$40/hour) to \$72.00 (108 minutes or 1.8 hours x \$40/hour) per reported case. With respect to how many cases an eligible professional would

report when using the claims-based reporting mechanism, we proposed that an eligible professional would need to report on 50 percent of the eligible professional's applicable cases. The actual number of cases on which an eligible professional would report would vary depending on the number of the eligible professional's applicable cases. However, in prior years, when the reporting threshold was 80 percent, we found that the median number of reporting cases for each measure was 9. Since we are reducing the reporting threshold to 50 percent, we estimated that the average number of reporting cases for each measure would be reduced to 6. Based on these estimates, we estimated that the total cost of reporting for an eligible professional choosing the claims-based reporting mechanism would range from (\$1.50/per reported case x 6 reported cases) \$9.00 to (\$72.00/reported case x 6 reported cases) \$432.

With respect to an eligible professional or group practice who participates in the PQRS via a qualified registry, direct EHR product, EHR data submission vendor product, or qualified clinical data registry, we believe there would be little to no burden associated for an eligible professional or group practice to report PQRS quality measures data to CMS, because the selected reporting mechanism submits the quality measures data for the eligible professional. Although we noted that there may be start-up costs associated with purchasing a qualified registry, direct EHR product, EHR data submission vendor, or qualified clinical data registry, we believe that an eligible professional or group practice would not purchase a qualified registry, direct EHR product, EHR data submission vendor product, or qualified clinical data registry solely for the purpose of reporting PQRS quality measures. Therefore, we have not included the cost of purchasing a qualified registry, direct EHR, EHR data submission vendor product, or qualified clinical data registry in our burden estimates.

Unlike eligible professionals who choose to report individually, we noted that eligible professionals choosing to participate as part of a group practice under the GPRO must indicate their intent to participate in the PORS as a group practice. The total burden for group practices who submit PQRS quality measures data via the proposed GPRO web-interface would be the time and effort associated with submitting this data. To submit quality measures data for the PORS, a group practice would need to (1) be selected to participate in the PORS GPRO and (2) report quality measures data. With respect to the administrative duties for being selected to participate in the PORS as a GPRO, we believe it would take approximately 6 hours – including 2 hours to decide to participate in the PQRS as a GPRO, 2 hours to self-nominate, and 2 hours to undergo the vetting process with CMS officials – for a group practice to be selected to participate in the PQRS GPRO for the applicable year. Therefore, we estimated that the cost of undergoing the GPRO selection process would be (\$16/hour x 6 hours) \$96. With respect to reporting, the total reporting burden is the time and effort associated with the group practice submitting the quality measures data (that is, completed the data collection interface). Based on burden estimates for the PGP demonstration, which uses the same data submission methods, we estimated the burden associated with a group practice completing the data collection interface would be approximately 79 hours. Therefore, we estimated that the report cost for a group practice to submit PQRS quality measures data for the proposed reporting options in an applicable year would be (\$40/hour x 79 hours) \$3,160.

Aside from the burden of eligible professionals and group practices participating in the PQRS, we believe that vendors of registries, qualified clinical data registries, direct EHR products, and EHR data submission vendor products incur costs associated with participating in the PQRS. Please note that we finalized requirements for a new reporting mechanism in this CY

2014 PFS final rule with comment period – the qualified clinical data registry. For purposes of these burden estimates, we believe that, at least in its initial stage, vendors of a qualified clinical data registry would have burden estimates similar to traditional registries, as we believe many of the vendors seeking to become qualified as a clinical data registry in the PQRS will be existing qualified registries.

With respect to qualified registries and qualified clinical data registries, the total burden for qualified registries who submit PQRS Quality Measures Data would be the time and effort associated with submitting this data. To submit quality measures data for the proposed program years for PQRS, a registry would need to (1) become qualified for the applicable year and (2) report quality measures data on behalf of its eligible professionals. With respect to administrative duties related to the qualification process for both traditional registries and clinical data registries, we estimated that it will take a total of 10 hours – including 1 hour to complete the self-nomination statement, 2 hours to interview with CMS, 2 hours to calculate numerators, denominators, and measure results for each measure the registry wishes to report using a CMS-provided measure flow, and 5 hours to complete an XML submission – to become qualified to report PQRS quality measures data. Therefore, we estimated that it would cost a traditional registry and clinical data registry (\$16.00/hour x 10 hours) \$160 to become qualified to submit PQRS quality measures data on behalf of its eligible professionals.

With respect to the reporting of quality measures data, we believe the burden associated with reporting is the time and effort associated with the registry calculating quality measures results from the data submitted to the registry by its eligible professionals, submitting numerator and denominator data on quality measures, and calculating these measure results. We believe, however, that registries already perform these functions for its eligible professionals irrespective

of participating in the PQRS. Therefore, we believe there would be little to no additional burden associated with reporting PQRS quality measures data. Whether there is any additional reporting burden will vary with each registry, depending on the registry's level of savvy with submitting quality measures data for the PQRS.

With respect to EHR products, the total burden for direct EHR products and EHR data submission vendors who submit PQRS Quality Measures Data would be the time and effort associated with submitting this data. To submit quality measures data for a program year under the PQRS, a direct EHR product or EHR data submission vendor would need to report quality measures data on behalf of its eligible professionals. Please note that we do not require direct EHR products and EHR data submission vendors to become qualified to submit PQRS quality measures data.

In addition to the GPRO web interface, please note that we have established a new reporting mechanism that would be available to group practices comprised of 25-99 eligible professionals: the certified survey vendor. With respect to using a certified survey vendor, we believe there would be little to no burden associated for a group practice to report the CG CAHPS survey data to CMS, because the selected reporting mechanism submitted the quality measures data for the group practice. Although there may be start-up costs associated with purchasing a certified survey vendor, we believe that a group practice would not purchase a certified survey vendor solely for the purpose of reporting the CG CAHPS survey for the PQRS. Therefore, we have not included the cost of purchasing a certified survey vendor in our burden estimates.

TABLE 95: Estimated Costs for Reporting PQRS Quality Measures Data per Eligible Professional

	Estimated	Estimated	Number of	Hourly	Total Cost
	Hours	Cases	Measures	Rate	
Individual Eligible	5.0	1	N/A	\$16	\$80
Professional (EP):					
Preparation					
Individual EP: Claims	1.8	6	9	\$40	\$3,888
Individual EP: Registry	N/A	1	N/A	N/A	Minimal
Individual EP: EHR	N/A	1	N/A	N/A	Minimal
Group Practice: Self-	6.0	1	N/A	\$16	\$96
Nomination					
Group Practice: Reporting	79	1	N/A	\$40	\$3,160

TABLE 96: Estimated Costs per Vendor to Participate in the PQRS

	Estimated Hours	Hourly Rate	Total Cost
Registry: Self-Nomination	10	\$16	\$160

10. Medicare EHR Incentive Program

Please note that the requirements for meeting the clinical quality measures (CQM) component of achieving meaningful use for the EHR Incentive Program in 2014 were established in a standalone final rule published on September 4, 2012 (77 FR 53968). The proposals contained in this CY 2014 PFS final rule with comment period merely propose alternative methods to report CQMs to meet the CQM component of achieving meaningful use for the EHR Incentive Program in 2014. We believe any impacts these proposals would have are absorbed in the impacts discussion published in the EHR Incentive Program final rule published on September 4, 2012.

11. Medicare Shared Savings Program

Please note that the requirements for participating in the Medicare Shared Saving

Program and the impacts of these requirements were established in the final rule for the

Medicare Shared Savings Program that appeared in the **Federal Register** on November 2, 2011

(76 FR 67962). The proposals for the Medicare Shared Savings Program set forth in the CY 2014 final rule with comment period expand the incorporation of reporting requirements and incentive payments related to PQRS under section 1848 to include reporting requirements related to the payment adjustment. Since ACO participants and ACO provider/suppliers will not have to report PQRS separately to avoid the payment adjustment, this reduces the quality reporting burden for ACO participants participating in the Shared Savings Program. There is no impact for the additional proposals related to requirements for setting benchmarks or for scoring the CAHPS measure modules.

12. Physician Value-Based Payment Modifier and the Physician Feedback Reporting Program

The changes to the Physician Feedback Program in section III.K. of this final rule with comment period would not impact CY 2014 physician payments under the Physician Fee Schedule. We anticipate that as we approach implementation of the value modifier, physicians will increasingly participate in the Physician Quality Reporting System to determine and understand how the value modifier could affect their payments.

13. Existing Standards for E-prescribing under Medicare Part D and Identification

This section of the final rule with comment period imposes no new requirements because use of the official Part D e-prescreening standards; NCPDP SCRIPT 10.6, Formulary and Benefit 3.0 are voluntary, and as such, it will not have a significant economic impact on a substantial number of small entities, small rural hospitals or state, local, or tribal governments or on the private sector.

14. Chiropractic Services Demonstration

As discussed in section III.M. of this final rule with comment period, we are continuing the recoupment of the \$50 million in expenditures from this demonstration in order to satisfy the

BN requirement in section 651(f)(1)(B) of the MMA. We initiated this recoupment in CY 2010 and this will be the fifth and final year. As discussed in the CY 2010 PFS final rule with comment period, we finalized a policy to recoup \$10 million each year through adjustments to payments under the PFS for chiropractic CPT codes in CYs 2010 through 2014. For each year of this recoupment, we have provided OACT's projected chiropractic expenditures based on previous year's data. Although OACT's projections have included the statutory reductions to physician payments, the statute was amended in each year to avoid these reductions. As a result, Medicare expenditures for chiropractic services during the recoupment were higher than the OACT projections. Chiropractic services expenditures during the recoupment period have been as follows: \$540 million in 2010; \$520 million in 2011; and \$580 million in 2012. In total, CMS recouped \$32.8 million over the years of 2010, 2011 and 2012. OACT now projects chiropractic expenditures to be approximately \$580 million in 2013. A 2 percent recoupment percentage for chiropractic services would result in approximately \$11.6 million in 2013. For the years 2010 through 2013, CMS would have recouped approximately \$44.4 million of the \$50 million required for budget neutrality.

CMS plans to recoup the remaining funds, approximately \$5.6 million, and will reduce chiropractic CPT codes (CPT codes 98940, 98941, and 98942) by the appropriate percentage.

G. Alternatives Considered

This final rule with comment period contains a range of policies, including some provisions related to specific statutory provisions. The preceding preamble provides descriptions of the statutory provisions that are addressed, identifies those policies when discretion has been exercised, presents rationale for our final policies and, where relevant, alternatives that were considered.

H. Impact on Beneficiaries

There are a number of changes in this final rule with comment period that would have an effect on beneficiaries. In general, we believe that many of the changes, including the refinements of the PQRS with its focus on measuring, submitting, and analyzing quality data; establishing the basis for the value-based payment modifier to adjust physician payment beginning in CY 2015; improved accuracy in payment through revisions to the inputs used to calculate payments under the PFS; and revisions to payment for Part B drugs will have a positive impact and improve the quality and value of care provided to Medicare beneficiaries.

Most of the aforementioned policy changes could result in a change in beneficiary liability as relates to coinsurance (which is 20 percent of the fee schedule amount if applicable for the particular provision after the beneficiary has met the deductible). To illustrate this point, as shown in Table 94, the CY 2013 national payment amount in the nonfacility setting for CPT code 99203 (Office/outpatient visit, new) is \$108.05, which means that in CY 2013 a beneficiary would be responsible for 20 percent of this amount, or \$21.61. Based on this final rule with comment period, using the current (CY 2013) CF of 34.0376, adjusted to 35.6446 to include budget neutrality, the CY 2014 national payment amount in the nonfacility setting for CPT code 99203, as shown in Table 94, is \$107.95, which means that, in CY 2014, the beneficiary coinsurance for this service would be \$21.59.

I. Accounting Statement

As required by OMB Circular A-4 (available at

http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf), in Table 97 (Accounting Statement), we have prepared an accounting statement showing the estimated expenditures associated with this final rule with comment period. This estimate includes the CY 2014 incurred benefit impact

associated with the estimated CY 2014 PFS conversion factor update based on the FY 2014 President's Budget baseline.

TABLE 97: Accounting Statement: Classification of Estimated Expenditures

CATEGORY	TRANSFERS
CY 2014 Annualized Monetized Transfers	Estimated decrease in expenditures of \$18.8 billion
	for PFS conversion factor update.
From Whom To Whom?	Federal Government to physicians, other
	practitioners and providers and suppliers who receive
	payment under Medicare.
CY 2014 Annualized Monetized Transfers	Estimated increase in payment of \$286 million.
From Whom To Whom?	Federal Government to eligible professionals who
	satisfactorily participate in the Physician Quality
	Reporting System (PQRS).
CY 2014 Annualized Monetized Transfers	Estimated decrease in expenditures of \$50 million
	for liability for overpayments to or on behalf of
	individuals including payments to providers or other
	persons.
From Whom To Whom?	Federal Government to physicians, other
	practitioners and providers and suppliers who receive
	payment under Medicare.

TABLE 98: Accounting Statement: Classification of Estimated Costs, Transfer, and Savings

Savings				
Category	Transfer			
CY 2014 Annualized Monetized	-\$29 million			
Transfers of beneficiary cost				
coinsurance.				
From Whom to Whom?	Beneficiaries to Physicians and			
	Nonphysician Practitioners			
Category	Cost			
CY 2014 Annualized Monetized	\$66.6 million			
Cost to eligible professionals of				
Participating in the PQRS				
Program				

J. Conclusion

The analysis in the previous sections, together with the remainder of this preamble, provides an initial "Regulatory Flexibility Analysis." The previous analysis, together with the

preceding portion of this preamble, provides a Regulatory Impact Analysis.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medical devices, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 410

Health facilities, Health professions, Kidney diseases, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 411

Kidney diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 414

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Health professionals, Incorporation by Reference, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 425

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 405--FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

1. The authority citation for part 405 continues to read as follows:

Authority: Secs. 205(a), 1102, 1861, 1862(a), 1862(m), 1869, 1871, 1874, 1881, and 1886(k) of the Social Security Act (42 U.S.C. 405(a), 1302, 1395x, 1395y(a), 1395y(m), 1395ff, 1395hh, 1395kk, 1395rr and 1395ww(k)), and sec. 353 of the Public Health Service Act (42 U.S.C. 263a).

- 2. Section 405.201 is amended by:
- A. Revising paragraph (a)(2).
- B. Adding paragraph (a)(3).
- C. Revising paragraph (b).

The revisions and addition read as follows:

§405.201 Scope of subpart and definitions.

- (a) * * *
- (2) CMS may consider for Medicare coverage certain devices with an FDA-approved investigational device exemption (IDE) that have been categorized as Category B (Nonexperimental/investigational) device.
 - (3) CMS identifies criteria for coverage of items and services furnished in IDE studies.
 - (b) Definitions. As used in this subpart—

<u>Category A (Experimental) device</u> refers to a device for which "absolute risk" of the device type has not been established (that is, initial questions of safety and effectiveness have not been resolved) and the FDA is unsure whether the device type can be safe and effective.

<u>Category B (Nonexperimental/investigational) device</u> refers to a device for which the incremental risk is the primary risk in question (that is, initial questions of safety and effectiveness of that device type have been resolved), or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA premarket approval or clearance for that device type.

<u>ClinicalTrials.gov</u> refers to the National Institutes of Health's National Library of Medicine's online registry and results database of publicly and privately supported clinical studies of human participants conducted around the world.

<u>Contractors</u> refers to Medicare Administrative Contractors and other entities that contract with CMS to review and adjudicate claims for Medicare payment of items and services.

Investigational device exemption (IDE) refers to an FDA-approved IDE application that permits a device, which would otherwise be subject to marketing approval or clearance, to be shipped lawfully for the purpose of conducting a clinical study in accordance with 21 U.S.C. 360j(g) and 21 CFR part 812.

Routine care items and services refers to items and services that are otherwise generally available to Medicare beneficiaries (that is, a benefit category exists, it is not statutorily excluded, and there is no national noncoverage decision) that are furnished during a clinical study and that would be otherwise furnished even if the beneficiary were not enrolled in a clinical study.

3. Section 405.203 is amended by revising paragraphs (a)(1) and (2) and (b) to read as follows:

§405.203 FDA categorization of investigational devices.

(a) * * *

- (1) Category A (Experimental) devices.
- (2) Category B (Nonexperimental/investigational) devices.
- (b) The FDA notifies CMS, when it notifies the sponsor, that the device is categorized by FDA as Category A (Experimental) or Category B (Nonexperimental).

* * * * * *

4. Section 405.205 is amended by revising the section heading and paragraph (a)(1) to read as follows:

§405.205 Coverage of a Category B (Nonexperimental/investigational) device.

- (a) * * *
- (1) The FDA notifies CMS, when it notifies the sponsor, that the device is categorized by FDA as Category B (Nonexperimental/investigational).

* * * * *

5. Section 405.207 is amended by revising paragraphs (b)(2) and (3) to read as follows: §405.207 Services related to a non-covered device.

* * * * * * (b) * * *

- (2) Routine care items and services related to Category A (Experimental) devices as defined in § 405.201(b), and furnished in conjunction with FDA-approved clinical studies that meet the coverage requirements in §405.211.
- (3) Routine care items and services related to Category B

 (Nonexperimental/investigational) devices as defined in § 405.201(b), and furnished in conjunction with FDA-approved clinical studies that meet the coverage requirements in § 405.211.
 - 6. Section 405.209 is revised to read as follows:

§405.209 Payment for a Category B (Nonexperimental/investigational) device.

Payment under Medicare for a Category B (Nonexperimental/investigational) device is based on, and may not exceed, the amount that would have been paid for a currently used device serving the same medical purpose that has been approved or cleared for marketing by the FDA.

7. Section 405.211 is revised to read as follows:

§405.211 Coverage of items and services in FDA-approved IDE studies.

- (a) <u>Coverage of routine care items and services for Category A (Experimental) devices.</u>

 Medicare covers routine care items and services furnished in an FDA-approved Category A

 (Experimental) IDE study if CMS (or its designated entity) determines that the Medicare coverage IDE study criteria in § 405.212 are met.
- (b) Coverage of Category B (Nonexperimental/investigational) IDE devices and routine care items and services. Medicare may make payment for a Category B (Nonexperimental/investigational) IDE device and routine care items and services furnished in an FDA-approved Category B (Nonexperimental/investigational) IDE study if CMS (or its designated entity) determines prior to the submission of the first related claim that the Medicare coverage IDE study criteria in §405.212 are met.
- (c) CMS (or its designated entity) must review the following to determine if the Medicare coverage IDE study criteria in § 405.212 are met for purposes of coverage of items and services described in paragraphs (a) and (b) of this section:
 - (1) FDA approval letter of the IDE.
 - (2) IDE study protocol.
 - (3) IRB approval letter.
 - (4) NCT number.
 - (5) Supporting materials, as needed.

(d) <u>Notification</u>. A listing of all CMS-approved Category A (Experimental) IDE studies and Category B (Nonexperimental/investigational) IDE studies shall be posted on the CMS website and published in the **Federal Register**.

8. Section 405.212 is added to read as follows:

§405.212 Medicare Coverage IDE study criteria.

- (a) For Medicare coverage of items and services described in § 405.211, a Category A (Experimental) or Category B (Nonexperimental/investigational) IDE study must meet all of the following criteria:
- (1) The principal purpose of the study is to test whether the device improves health outcomes of appropriately selected patients.
- (2) The rationale for the study is well supported by available scientific and medical information, or it is intended to clarify or establish the health outcomes of interventions already in common clinical use.
 - (3) The study results are not anticipated to unjustifiably duplicate existing knowledge.
- (4) The study design is methodologically appropriate and the anticipated number of enrolled subjects is adequate to confidently answer the research question(s) being asked in the study.
- (5) The study is sponsored by an organization or individual capable of successfully completing the study.
- (6) The study is in compliance with all applicable Federal regulations concerning the protection of human subjects found at 21 CFR parts 50, 56, and 812 and 45 CFR part 46.
- (7) Where appropriate, the study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Studies of all medical technologies measuring

therapeutic outcomes as one of the objectives may be exempt from this criterion only if the disease or condition being studied is life threatening and the patient has no other viable treatment options.

- (8) The study is registered with the National Institutes of Health's National Library of Medicine's ClinicalTrials.gov.
- (9) The study protocol describes the method and timing of release of results on all prespecified outcomes, including release of negative outcomes and that the release should be hastened if the study is terminated early.
- (10) The study protocol must describe how Medicare beneficiaries may be affected by the device under investigation, and how the study results are or are not expected to be generalizable to the Medicare beneficiary population. Generalizability to populations eligible for Medicare due to age, disability, or other eligibility status must be explicitly described.
 - (b) [Reserved]
 - 9. Section 405.213 is amended by revising paragraph (a)(1) to read as follows:

§405.213 Re-evaluation of a device categorization.

- (a) * * *
- (1) Any sponsor that does not agree with an FDA decision that categorizes its device as Category A (experimental) may request re-evaluation of the categorization decision.
- * * * * *
- 10. Section 405.350 is amended by revising paragraph (c) to read as follows: §405.350 Individual's liability for payments made to providers and other persons for items and services furnished the individual.

* * * * *

(c) For purposes of paragraph (a)(2) of this section, a provider of services or other person must, in the absence of evidence to the contrary, be deemed to be without fault if the determination of the carrier, the intermediary, or the Centers for Medicare & Medicaid Services that more than the correct amount was paid was made subsequent to the fifth year following the year in which notice was sent to such individual that such amount had been paid.

11. Section 405.355 is amended by revising paragraph (b) to read as follows:

§405.355 Waiver of adjustment or recovery.

* * * * *

- (b) Adjustment or recovery of an incorrect payment (or only such part of an incorrect payment as may be determined to be inconsistent with the purposes of Title XVIII of the Act) against an individual who is without fault will be deemed to be against equity and good conscience if the incorrect payment was made for items and services that are not payable under section 1862(a)(1) or (a)(9) of the Act and if the determination that such payment was incorrect was made subsequent to the fifth year following the year in which notice of such payment was sent to such individual.
 - 12. Section 405.2413 is amended by—
 - A. Redesignating paragraphs (a)(4) and (5) as paragraphs (a)(5) and (6), respectively.
 - B. Adding new paragraph (a)(4).
 - C. Revising newly redesignated paragraph (a)(5).

The revision and addition reads as follows:

§405.2413 Services and supplies incident to a physician's services.

- (a) * * *
- (4) Services and supplies must be furnished in accordance with applicable State law;

(5) Furnished under the direct supervision of a physician; and
* * * * *
13. Section 405.2415 is amended by—
A. Redesignating paragraphs (a)(4) and (5) as paragraphs (a)(5) and (6), respectively.
B. Adding new paragraph (a)(4).
C. Revising newly redesignated paragraph (a)(5).
D. Revising paragraph (b).
The revision and addition reads as follows:
§405.2415 Services and supplies incident to nurse practitioner and physician assistant
services.
(a) * * * *
(4) Services and supplies must be furnished in accordance with applicable State law;
(5) Furnished under the direct supervision of a nurse practitioner, physician assistant,
nurse midwife, specialized nurse practitioner or a physician; and
* * * * *
(b) The direct supervision requirement is met in the case of a nurse practitioner, physician
assistant, nurse midwife, or specialized nurse practitioner only if such a person is permitted to
supervise such services under the written policies governing the rural health clinic.
* * * * *
14. Section 405.2452 is amended by—
A. Redesignating paragraphs (a)(4) and (5) as paragraphs (a)(5) and (6), respectively.
B. Adding new paragraph (a)(4).
C. Revising newly redesignated paragraph (a)(5).

D. Revising paragraph (b).

The revision and addition reads as follows:

§405.2452 Services and supplies incident to clinical psychologist and clinical social worker services.

- (a) * * *
- (4) Services and supplies must be furnished in accordance with applicable State law;
- (5) Furnished under the direct supervision of a clinical psychologist, clinical social worker or physician; and
 - * * * * *
 - (b) The direct supervision requirement in paragraph (a)(5) of this section is met only if the clinical psychologist or clinical social worker is permitted to supervise such services under the written policies governing the federally qualified health center.

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

15. The authority citation for part 410 continues to read as follows:

Authority: Secs. 1102, 1834, 1871, 1881, and 1893 of the Social Security Act (42 U.S.C. 1302. 1395m, 1395hh, and 1395ddd).

§410.19 [Amended]

- 16. In §410.19(a) amend the definition of "eligible beneficiary" by removing paragraph (1) and redesignating paragraphs (2) and (3) as paragraphs (1) and (2), respectively.
 - 17. Section 410.26 is amended by—
 - A. Revising paragraph (a)(1).
 - B. Redesignating paragraph (b)(7) and (8) as paragraph (b)(8) and (9), respectively.
 - C. Adding new paragraph (b)(7).

The revision and addition reads as follows:

§410.26 Services and supplies incident to a physician's professional services: Conditions.

(a) *	*	*
-------	---	---

(1) <u>Auxiliary personnel</u> means any individual who is acting under the supervision of a physician (or other practitioner), regardless of whether the individual is an employee, leased employee, or independent contractor of the physician (or other practitioner) or of the same entity that employs or contracts with the physician (or other practitioner) and meets any applicable requirements to provide the services, including licensure, imposed by the State in which the services are being furnished.

- * * * * *
- (b) * * *
- (7) Services and supplies must be furnished in accordance with applicable State law.
- * * * * *
- 18. Section 410.37 is amended by revising paragraph (b) to read as follows:

§410.37 Colorectal cancer screening tests: Conditions for and limitations on coverage.

* * * * *

(b) <u>Condition for coverage of screening fecal-occult blood tests</u>. Medicare Part B pays for a screening fecal-occult blood test if it is ordered in writing by the beneficiary's attending physician, physician assistant, nurse practitioner, or clinical nurse specialist.

* * * * *

- 19. Section 410.59 is amended by—
- A. Adding paragraph (e)(1)(iv).
- B. Revising paragraph (e)(2)(iv).

C. Adding paragraph (e)(2)(v).

The revision and additions reads as follows:

§410.59 Outpatient occupational therapy services: Conditions.

* * * * *

- (e) * * *
- (1)***
- (iv) Outpatient occupational therapy services furnished by a CAH directly or under arrangements must be counted towards the annual limitation on incurred expenses as if such services were paid under section 1834(k)(1)(b) of the Act.
 - (2)* * *
- (iv) Outpatient occupational therapy services furnished by a nurse practitioner, clinical nurse specialist, or physician assistant or incident to their services; and
- (v) Outpatient occupational therapy services furnished by a CAH directly or under arrangements.

* * * * *

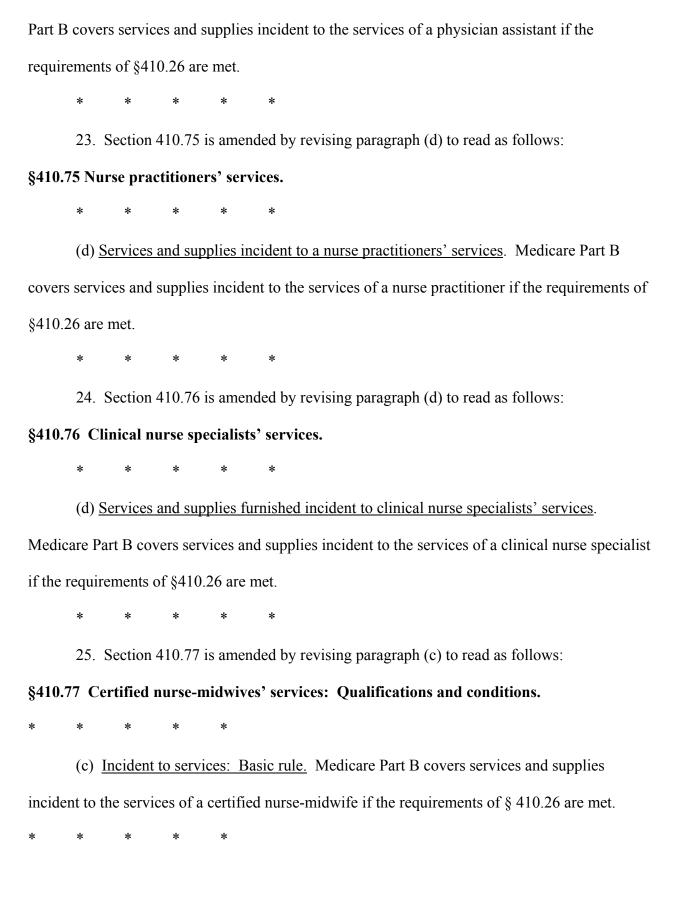
- 20. Section 410.60 is amended by—
- A. Adding paragraph (e)(1)(iv).
- B. Revising paragraph (e)(2)(v).
- C. Adding paragraph (e)(2)(vi).
- D. In paragraph (e)(3), removing the phrase "or CAH".

The additions and revision read as follows:

§410.60 Outpatient physical therapy services: Conditions.

* * * * *

CMS-1600-FC	1320
(e)* * *	
(1)* * *	
(iv) Outpatient physical therapy and speech-language pathology services fu	rnished by a
CAH directly or under arrangements must be counted towards the annual limitation	n on incurred
expenses as if such services were paid under section 1834(k)(1)(b) of the Act.	
(2) * * *	
(v) Outpatient physical therapy and speech-language pathology services fur	nished by a
nurse practitioner, clinical nurse specialist, or physician assistant or incident to their	ir services;
and	
(vi) Outpatient physical therapy and speech-language pathology services fu	rnished by a
CAH directly or under arrangements.	
* * * * *	
21. Section 410.71 is amended by revising paragraph (a)(2) to read as follows:	ows:
§410.71 Clinical psychologist services and services and supplies incident to cli	nical
psychologist services.	
(a) * * * *	
(2) Medicare Part B covers services and supplies incident to the services of	a clinical
psychologist if the requirements of §410.26 are met.	
* * * * *	
22. Section 410.74 is amended by revising paragraph (b) to read as follows	3:
§410.74 Physician assistants' services.	
* * * * *	
(b) Services and supplies furnished incident to a physician assistant's services	ces. Medicare



26. Section 410.78 is amended by revising paragraph (b) introductory text and paragraph (b)(4) to read as follows:

§ 410.78 Telehealth services.

* * * * *

(b) General rule. Medicare Part B pays for office or other outpatient visits, subsequent hospital care services (with the limitation of one telehealth visit every three days by the patient's admitting physician or practitioner), subsequent nursing facility care services (not including the Federally-mandated periodic visits under § 483.40(c) of this chapter and with the limitation of one telehealth visit every 30 days by the patient's admitting physician or nonphysician practitioner), professional consultations, psychiatric diagnostic interview examination, neurobehavioral status exam, individual psychotherapy, pharmacologic management, end-stage renal disease-related services included in the monthly capitation payment (except for one "hands on" visit per month to examine the access site), individual and group medical nutrition therapy services, individual and group kidney disease education services, individual and group diabetes self-management training services (except for one hour of "hands on" services to be furnished in the initial year training period to ensure effective injection training), individual and group health and behavior assessment and intervention services, smoking cessation services, alcohol and/or substance abuse and brief intervention services, screening and behavioral counseling interventions in primary care to reduce alcohol misuse, screening for depression in adults, screening for sexually transmitted infections (STIs) and high intensity behavioral counseling (HIBC) to prevent STIs, intensive behavioral therapy for cardiovascular disease, behavioral counseling for obesity, and transitional care management services furnished by an interactive telecommunications system if the following conditions are met:

* * * * *

- (4) Originating sites must be:
- (i) Located in a health professional shortage area (as defined under section 332(a)(1)(A) of the Public Health Service Act (42 U.S.C. 254e(a)(1)(A)) that is either outside of a Metropolitan Statistical Area (MSA) as of December 31st of the preceding calendar year or within a rural census tract of an MSA as determined by the Office of Rural Health Policy of the Health Resources and Services Administration as of December 31st of the preceding calendar year, or
- (ii) Located in a county that is not included in a Metropolitan Statistical Area as defined in section 1886(d)(2)(D) of the Act as of December 31st of the preceding year, or
- (iii) An entity participating in a Federal telemedicine demonstration project that has been approved by, or receive funding from, the Secretary as of December 31, 2000, regardless of its geographic location.

* * * * *

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

27. The authority citation for part 411 continues to read as follows:

Authority: Secs. 1102, 1860D-1 through 1860D-42, 1871, and 1877 of the Social Security Act (42 U.S.C. 1302, 1395w-101 through 1395w-152, 1395hh, and 1395nn).

28. Section 411.15 is amended by revising paragraphs (o)(1) and (2) to read as follows: §411.15 Particular services excluded from coverage.

* * * * *

(o) * * *

(1) Categorized by the FDA as a Category B (Nonexperimental/investigational) device as defined in §405.201(b) of the chapter; and

(2) Furnished in accordance with the coverage requirements in §405.211(b).

* * * * *

PART 414-PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

29. The authority citation for part 414 continues to read as follows:

Authority: Secs. 1102, 1871, and 1881(b)(l) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr(b)(l)).

30. Section 414.65 is amended by revising paragraph (a)(1) to read as follows:

§414.65 Payment for telehealth services.

- (a) * * *
- (1) The Medicare payment amount for office or other outpatient visits, subsequent hospital care services (with the limitation of one telehealth visit every 3 days by the patient's admitting physician or practitioner), subsequent nursing facility care services (with the limitation of one telehealth visit every 30 days by the patient's admitting physician or nonphysician practitioner), professional consultations, psychiatric diagnostic interview examination, neurobehavioral status exam, individual psychotherapy, pharmacologic management, end-stage renal disease-related services included in the monthly capitation payment (except for one "hands on" visit per month to examine the access site), individual and group medical nutrition therapy services, individual and group kidney disease education services, individual and group diabetes self-management training services (except for one hour of "hands on" services to be furnished in the initial year training period to ensure effective injection training), individual and group health and behavior assessment and intervention, smoking cessation services, alcohol and/or substance

abuse and brief intervention services, screening and behavioral counseling interventions in primary care to reduce alcohol misuse, screening for depression in adults, screening for sexually transmitted infections (STIs) and high intensity behavioral counseling (HIBC) to prevent STIs, intensive behavioral therapy for cardiovascular disease, behavioral counseling for obesity, and transitional care management services furnished via an interactive telecommunications system is equal to the current fee schedule amount applicable for the service of the physician or practitioner.

- (i) Emergency department or initial inpatient telehealth consultations. The Medicare payment amount for emergency department or initial inpatient telehealth consultations furnished via an interactive telecommunications system is equal to the current fee schedule amount applicable to initial hospital care provided by a physician or practitioner.
- (ii) <u>Follow-up inpatient telehealth consultations</u>. The Medicare payment amount for follow-up inpatient telehealth consultations furnished via an interactive telecommunications system is equal to the current fee schedule amount applicable to subsequent hospital care provided by a physician or practitioner.

* * * * *

31. Section 414.90 is revised to read as follows:

§414.90 Physician Quality Reporting System (PQRS).

- (a) Basis and scope. This section implements the following provisions of the Act:
 - (1) 1848(a)--Payment Based on Fee Schedule.
 - (2) 1848(k)--Quality Reporting System.
 - (3) 1848(m)--Incentive Payments for Quality Reporting.
 - (b) Definitions. As used in this section, unless otherwise indicated--

Administrative claims means a reporting mechanism under which an eligible professional or group practice uses claims to report data on PQRS quality measures. Under this reporting mechanism, CMS analyzes claims data to determine which measures an eligible professional or group practice reports.

<u>Certified survey vendor</u> means a vendor that is certified by CMS for a particular program year to transmit survey measures data to CMS.

<u>Covered professional services</u> means services for which payment is made under, or is based on, the Medicare physician fee schedule as provided under section 1848(k)(3) of the Act and which are furnished by an eligible professional.

<u>Direct electronic health record (EHR) product</u> means an electronic health record vendor's product and version that submits data on PQRS measures directly to CMS.

<u>Electronic health record (EHR) data submission vendor product</u> means an entity that receives and transmits data on PQRS measures from an EHR product to CMS.

Eligible professional means any of the following:

- (i) A physician.
- (ii) A practitioner described in section 1842(b)(18)(C) of the Act.
- (iii) A physical or occupational therapist or a qualified speech-language pathologist.
- (iv) A qualified audiologist (as defined in section 1861(II)(3)(B) of the Act).

Group practice means a physician group practice that is defined by a TIN, with 2 or more individual eligible professionals (or, as identified by NPIs) that has reassigned their billing rights to the TIN.

Group practice reporting option (GPRO) web interface means a web product developed by CMS that is used by group practices that are selected to participate in the group practice

reporting option (GPRO) to submit data on PQRS quality measures.

Maintenance of Certification Program means a continuous assessment program, such as qualified American Board of Medical Specialties Maintenance of Certification Program or an equivalent program (as determined by the Secretary), that advances quality and the lifelong learning and self-assessment of board certified specialty physicians by focusing on the competencies of patient care, medical knowledge, practice-based learning, interpersonal and communication skills, and professionalism. Such a program must include the following:

- (i) The program requires the physician to maintain a valid unrestricted license in the United States.
- (ii) The program requires a physician to participate in educational and self-assessment programs that require an assessment of what was learned.
- (iii) The program requires a physician to demonstrate, through a formalized secure examination, that the physician has the fundamental diagnostic skills, medical knowledge, and clinical judgment to provide quality care in their respective specialty.
- (iv) The program requires successful completion of a qualified maintenance of certification program practice assessment.

<u>Maintenance of Certification Program Practice Assessment</u> means an assessment of a physician's practice that--

- (i) Includes an initial assessment of an eligible professional's practice that is designed to demonstrate the physician's use of evidence-based medicine.
 - (ii) Includes a survey of patient experience with care.
- (iii) Requires a physician to implement a quality improvement intervention to address a practice weakness identified in the initial assessment under paragraph (h) of this section and then

to remeasure to assess performance improvement after such intervention.

Measures group means a subset of four or more PQRS measures that have a particular clinical condition or focus in common. The denominator definition and coding of the measures group identifies the condition or focus that is shared across the measures within a particular measures group.

Physician Quality Reporting System (PQRS) means the physician reporting system under section 1848(k) of the Act for the reporting by eligible professionals of data on quality measures and the incentive payment associated with this physician reporting system.

<u>Performance rate</u> means the percentage of a defined population who receives a particular process of care or achieve a particular outcome for a particular quality measure.

Qualified clinical data registry means a CMS-approved entity that has self-nominated and successfully completed a qualification process that collects medical and/or clinical data for the purpose of patient and disease tracking to foster improvement in the quality of care provided to patients. A qualified clinical data registry must perform the following functions:

- (i) Submit quality measures data or results to CMS for purposes of demonstrating that, for a reporting period, its eligible professionals have satisfactorily participated in PQRS. A qualified clinical data registry must have in place mechanisms for the transparency of data elements and specifications, risk models, and measures.
- (ii) Submit to CMS, for purposes of demonstrating satisfactory participation, quality measures data on multiple payers, not just Medicare patients
- (iii) Provide timely feedback, at least four times a year, on the measures at the individual participant level for which the qualified clinical data registry reports on the eligible professional's behalf for purposes of the individual eligible professional's satisfactory

participation in the clinical quality data registry.

(iv) Possess benchmarking capacity that measures the quality of care an eligible professional provides with other eligible professionals performing the same or similar functions.

Qualified registry means a medical registry or a maintenance of certification program operated by a specialty body of the American Board of Medical Specialties that, with respect to a particular program year, has self-nominated and successfully completed a vetting process (as specified by CMS) to demonstrate its compliance with the PQRS qualification requirements specified by CMS for that program year. The registry may act as a data submission vendor, which has the requisite legal authority to provide PQRS data (as specified by CMS) on behalf of an eligible professional to CMS. If CMS finds that a qualified registry submits grossly inaccurate data for reporting periods occurring in a particular year, CMS reserves the right to disqualify a registry for reporting periods occurring in the subsequent year.

Reporting rate means the percentage of patients that the eligible professional indicated a quality action was or was not performed divided by the total number of patients in the denominator of the measure.

- (c) <u>Incentive payments</u>. For 2007 to 2014, with respect to covered professional services furnished during a reporting period by an eligible professional, an eligible professional (or in the case of a group practice under paragraph (i) of this section, a group practice) may receive an incentive if--
- (1) There are any quality measures that have been established under the PQRS that are applicable to any such services furnished by such professional (or in the case of a group practice under paragraph (i) of this section, such group practice) for such reporting period; and
 - (2) If the eligible professional (or in the case of a group practice under paragraph (j) of

this section, the group practice) satisfactorily submits (as determined under paragraph (g) of this section for the eligible professional and paragraph (i) of this section for the group practice) to the Secretary data on such quality measures in accordance with the PQRS for such reporting period, in addition to the amount otherwise paid under section 1848 of the Act, there also must be paid to the eligible professional (or to an employer or facility in the cases described in section 1842(b)(6)(A) of the Act or, in the case of a group practice under paragraph (i) of this section, to the group practice) from the Federal Supplementary Medical Insurance Trust Fund established under section 1841 of the Act an amount equal to the applicable quality percent (as specified in paragraph (c)(3) of this section) of the eligible professional's (or, in the case of a group practice under paragraph (i) of this section, the group practice's) total estimated allowed charges for all covered professional services furnished by the eligible professional (or, in the case of a group practice under paragraph (i) of this section, by the group practice) during the reporting period.

- (3) The applicable quality percent is as follows:
- (i) For 2007 and 2008, 1.5 percent.
- (ii) For 2009 and 2010, 2.0 percent.
- (iii) For 2011, 1.0 percent.
- (iv) For 2012, 2013, and 2014, 0.5 percent.
- (4) For purposes of this paragraph (c)--
- (i) The eligible professional's (or, in the case of a group practice under paragraph (i) of this section, the group practice's) total estimated allowed charges for covered professional services furnished during a reporting period are determined based on claims processed in the National Claims History (NCH) no later than 2 months after the end of the applicable reporting period;

(ii) In the case of the eligible professional who furnishes covered professional services in more than one practice, incentive payments are separately determined for each practice based on claims submitted for the eligible professional for each practice;

- (iii) Incentive payments to a group practice under this paragraph must be in lieu of the payments that would otherwise be made under the PQRS to eligible professionals in the group practice for meeting the criteria for satisfactory reporting for individual eligible professionals. For any program year in which the group practice (as identified by the TIN) is selected to participate in the PQRS group practice reporting option, the eligible professional cannot individually qualify for a PQRS incentive payment by meeting the requirements specified in paragraph (g) of this section.
- (iv) Incentive payments earned by the eligible professional (or in the case of a group practice under paragraph (i) of this section, by the group practice) for a particular program year will be paid as a single consolidated payment to the TIN holder of record.
- (5) The Secretary must treat an individual eligible professional, as identified by a unique TIN/NPI combination, as satisfactorily submitting data on quality measures (as determined under paragraph (g) of this section), if the eligible professional is satisfactorily participating (as determined under paragraph (h) of this section), in a qualified clinical data registry.
- (d) Additional incentive payment. Through 2014, if an eligible professional meets the requirements described in paragraph (d)(2) of this section, the applicable percent for such year, as described in paragraphs (c)(3)(iii) and (iv) of this section, must be increased by 0.5 percentage points.
- (1) In order to qualify for the additional incentive payment described in paragraph (d) of this section, an eligible professional must meet all of the following requirements:

(i) Satisfactorily submits data on quality measures, or, for 2014, in lieu of satisfactory reporting, satisfactorily participates in a qualified clinical data registry for purposes of this section for the applicable incentive year.

- (ii) Have such data submitted on their behalf through a Maintenance of Certification program that meets:
 - (A) The criteria for a registry (as specified by CMS); or
 - (B) An alternative form and manner determined appropriate by the Secretary.
- (iii) The eligible professional, more frequently than is required to qualify for or maintain board certification status--
 - (A) Participates in a maintenance of certification program for a year; and
- (B) Successfully completes a qualified maintenance of certification program practice assessment for such year.
- (2) In order for an eligible professional to receive the additional incentive payment, a Maintenance of Certification Program must submit to the Secretary, on behalf of the eligible professional, information--
- (i) In a form and manner specified by the Secretary, that the eligible professional has successfully met the requirements of paragraph (d)(1)(iii) of this section, which may be in the form of a structural measure.
 - (ii) If requested by the Secretary, on the survey of patient experience with care.
- (iii) As the Secretary may require, on the methods, measures, and data used under the Maintenance of Certification Program and the qualified Maintenance of Certification Program practice assessment.
 - (e) Payment adjustments. For 2015 and subsequent years, with respect to covered

professional services furnished by an eligible professional, if the eligible professional does not satisfactorily submit data on quality measures for covered professional services for the quality reporting period for the year (as determined under section 1848(m)(3)(A) of the Act), the fee schedule amount for such services furnished by such professional during the year (including the fee schedule amount for purposes for determining a payment based on such amount) must be equal to the applicable percent of the fee schedule amount that would otherwise apply to such services under this paragraph (e).

- (1) The applicable percent is as follows:
- (i) For 2015, 98.5 percent.
- (ii) For 2016 and each subsequent year, 98 percent.
- (2) The Secretary must treat an individual eligible professional, as identified by a unique TIN/NPI combination, as satisfactorily submitting data on quality measures (as determined under paragraph (h) of this section), if the eligible professional is satisfactorily participating, in a qualified clinical data registry.
- (f) <u>Use of appropriate and consensus-based quality measures</u>. For measures selected for inclusion in the PQRS quality measure set, CMS will use group practice measures determined appropriate by CMS and consensus-based quality measures that meet one of the following criteria.:
- (1) Be such measures selected by the Secretary from measures that have been endorsed by the entity with a contract with the Secretary under section 1890(a) of the Act. In the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration

is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

- (2) For each quality measure adopted by the Secretary under this paragraph, the Secretary ensures that eligible professionals have the opportunity to provide input during the development, endorsement, or selection of quality measures applicable to services they furnish.
- (g) <u>Use of quality measures for satisfactory participation in a qualified clinical data</u> registry. For measures selected for reporting to meet the criteria for satisfactory participation in a qualified clinical data registry, CMS will use measures selected by qualified clinical data registries based on parameters set by CMS.
- (h) <u>Satisfactory reporting requirements for the incentive payments</u>. In order to qualify to earn a PQRS incentive payment for a particular program year, an individual eligible professional, as identified by a unique TIN/NPI combination, must meet the criteria for satisfactory reporting specified by CMS under paragraph (h)(3) of (h)(5) of this section for such year by reporting on either individual PQRS quality measures or PQRS measures groups identified by CMS during a reporting period specified in paragraph (h)(1) of this section, using one of the reporting mechanisms specified in paragraph (h)(2) or (4) of this section, and using one of the reporting criteria specified in paragraph (h)(3) or (5) of this section.
 - (1) Reporting periods. For purposes of this paragraph, the reporting period is-
 - (i) The 12—month period from January 1 through December 31 of such program year.
 - (ii) A 6-month period from July 1 through December 31 of such program year.
- (A) For 2011, such 6-month reporting period is not available for EHR-based reporting of individual PQRS quality measures.
 - (B) For 2012 and subsequent program years, such 6-month reporting period from July 1

through December 31 of such program year is only available for registry-based reporting of PQRS measures groups by eligible professionals.

- (2) <u>Reporting mechanisms for individual eligible professionals</u>. An individual eligible professional who wishes to participate in the PQRS must report information on PQRS quality measures identified by CMS in one of the following manners:
- (i) <u>Claims</u>. Reporting PQRS quality measures or PQRS measures groups to CMS, by no later than 2 months after the end of the applicable reporting period, on the eligible professional's Medicare Part B claims for covered professional services furnished during the applicable reporting period.
- (A) If an eligible professional re-submits a Medicare Part B claim for reprocessing, the eligible professional may not attach a G-code at that time for reporting on individual PQRS measures or measures groups.
 - (B) [Reserved]
- (ii) <u>Registry</u>. Reporting PQRS quality measures or PQRS measures groups to a qualified registry in the form and manner and by the deadline specified by the qualified registry selected by the eligible professional. The selected registry must submit information, as required by CMS, for covered professional services furnished by the eligible professional during the applicable reporting period to CMS on the eligible professional's behalf.
- (iii) <u>Direct EHR product</u>. Reporting PQRS quality measures to CMS by extracting clinical data using a secure data submission method, as required by CMS, from a direct EHR product by the deadline specified by CMS for covered professional services furnished by the eligible professional during the applicable reporting period.
 - (iv) EHR data submission vendor. Reporting PQRS quality measures to CMS by

extracting clinical data using a secure data submission method, as required by CMS, from an EHR data submission vendor product by the deadline specified by CMS for covered professional services furnished by the eligible professional during the applicable reporting period.

- (v) Although an eligible professional may attempt to qualify for the PQRS incentive payment by reporting on both individual PQRS quality measures and measures groups, using more than one reporting mechanism (as specified in paragraph (g)(2) of this section), or reporting for more than one reporting period, he or she will receive only one PQRS incentive payment per TIN/NPI combination for a program year.
- (3) <u>Satisfactory reporting criteria for individual eligible professionals for the 2014 PQRS</u> incentive. An individual eligible professional who wishes to qualify for the 2014 PQRS incentive must report information on PQRS quality measures data in one of the following manners:
 - (i) Via Claims. For the 12-month 2014 PQRS incentive reporting period—
- (A) Report at least 9 measures covering at least 3 National Quality Strategy domains, and report each measure for at least 50 percent of the Medicare Part B FFS patients seen during the reporting period to which the measure applies; or if less than 9 measures covering at least 3 National Quality Strategy domains apply to the eligible professional, report 1 to 8 measures covering 1 to 3 National Quality Strategy domains and report each measure for at least 50 percent of the Medicare Part B FFS patients seen during the reporting period to which the measure applies. For an eligible professional who reports fewer than 9 measures covering at least 3 NQS domains via the claims-based reporting mechanism, the eligible professional would be subject to the Measures Applicability Validation process, which would allow us to determine whether an eligible professional should have reported quality data codes for additional measures

and/or covering additional National Quality Strategy domains. Measures with a 0 percent performance rate would not be counted.

- (B) [Reserved]
- (ii) <u>Via Qualified Registry</u>. (A) For the 12-month 2014 PQRS incentive reporting period—
- (1) Report at least 9 measures covering at least 3 of the National Quality Strategy domains report each measure for at least 50 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies; or, if less than 9 measures covering at least 3 NQS domains apply to the eligible professional, report 1 to 8 measures covering 1 to 3 National Quality Strategy domains for which there is Medicare patient data and report each measure for at least 50 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. For an eligible professional who reports fewer than 9 measures covering at least 3 NQS domains via the qualified registry-based reporting mechanism, the eligible professional will be subject to the Measures Applicability Validation process, which would allow us to determine whether an eligible professional should have reported on additional measures and/or measures covering additional National Quality Strategy domains. Measures with a 0 percent performance rate would not be counted.
- (2) Report at least 1 measures group and report each measures group for at least 20 patients, a majority of which much be Medicare Part B FFS patients. Measures with a 0 percent performance rate or measures groups containing a measure with a 0 percent performance rate will not be counted.
- (B) For the 6-month 2014 PQRS incentive reporting period, report at least 1 measures group and report each measures group for at least 20 patients, a majority of which much be Medicare Part B FFS patients. Measures groups containing a measure with a 0 percent performance rate will not be counted.

(iii) <u>Via EHR Direct Product</u>. For the 12-month 2014 PQRS incentive reporting period, report 9 measures covering at least 3 of the National Quality Strategy domains. If an eligible professional's CEHRT does not contain patient data for at least 9 measures covering at least 3 domains, then the eligible professional must report the measures for which there is Medicare patient data. An eligible professional must report on at least 1 measure for which there is Medicare patient data.

- (iv) <u>Via EHR Data Submission Vendor</u>. For the 12-month 2014 PQRS incentive reporting period, report 9 measures covering at least 3 of the National Quality Strategy domains. If an eligible professional's CEHRT does not contain patient data for at least 9 measures covering at least 3 domains, then the eligible professional must report the measures for which there is Medicare patient data. An eligible professional must report on at least 1 measure for which there is Medicare patient data.
- (4) Reporting mechanisms for group practices. With the exception of a group practice who wishes to participate in the PQRS using the certified survey vendor mechanism (as specified in paragraph (h)(4)(v) of this section), a group practice must report information on PQRS quality measures identified by CMS in one of the following reporting mechanisms:
- (i) <u>Web interface</u>. For 2013 and subsequent years, reporting PQRS quality measures to CMS using a CMS web interface in the form and manner and by the deadline specified by CMS.
- (ii) <u>Registry</u>. For 2013 and subsequent years, reporting on PQRS quality measures to a qualified registry in the form and manner and by the deadline specified by the qualified registry selected by the eligible professional. The selected registry must submit information, as required by CMS, for covered professional services furnished by the eligible professional during the applicable reporting period to CMS on the eligible professional's behalf.

(iii) <u>Direct EHR product</u>. For 2014 and subsequent years, reporting PQRS quality measures to CMS by extracting clinical data using a secure data submission method, as required by CMS, from a direct EHR product by the deadline specified by CMS for covered professional services furnished by the eligible professional during the applicable reporting period.

- (iv) EHR data submission vendor. For 2014 and subsequent years, reporting PQRS quality measures to CMS by extracting clinical data using a secure data submission method, as required by CMS, from an EHR data submission vendor product by the deadline specified by CMS for covered professional services furnished by the eligible professional during the applicable reporting period.
- (v) <u>Certified survey vendors</u>. For 2014 and subsequent years, reporting CAHPS survey measures to CMS using a vendor that is certified by CMS for a particular program year to transmit survey measures data to CMS. Group practices that elect this reporting mechanism must select an additional group practice reporting mechanism in order to meet the criteria for satisfactory reporting for the incentive payments.
- (vi) Although a group practice may attempt to qualify for the PQRS incentive payment by using more than one reporting mechanism (as specified in paragraph (g)(3) of this section), or reporting for more than one reporting period, the group practice will receive only one PQRS incentive payment for a program year.
- (5) <u>Satisfactory reporting criteria for group practices for the 2014 PQRS incentive</u>. A group practice who wishes to qualify for the 2014 PQRS incentive must report information on PQRS quality measures identified by CMS in one of the following manners:
- (i) <u>Via the GPRO web interface</u>. (A) For the 12-month 2014 PQRS incentive reporting period, for a group practice of 25 to 99 eligible professionals, report on all measures included in

the web interface and populate data fields for the first 218 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 218, then report on 100 percent of assigned beneficiaries.

- (B) For the 12-month 2014 PQRS incentive reporting period, for a group practice of 100 or more eligible professionals, report on all measures included in the web interface and populate data fields for the first 411 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 411, then report on 100 percent of assigned beneficiaries. In addition, for the 12-month 2014 PQRS incentive reporting period, the group practice must report all CG CAHPS survey measures via a CMS-certified survey vendor, and report at least 6 measures covering at least 2 of the National Quality Strategy domains using a qualified registry, direct EHR product, or EHR data submission vendor.
- (ii) Via Qualified Registry. For the 12-month 2014 PQRS incentive reporting period, for a group practice of 2 or more eligible professionals, report at least 9 measures, covering at least 3 of the National Quality Strategy domains and report each measure for at least 50 percent of the group practice's Medicare Part B FFS patients seen during the reporting period to which the measure applies; or, if less than 9 measures covering at least 3 NQS domains apply to the group practice, then the group practice must report 1-8 measures for which there is Medicare patient data and report each measure for at least 50 percent of the group practice's Medicare Part B FFS patients seen during the reporting period to which the measure applies. For a group practice who reports fewer than 9 measures covering at least 3 NQS domains via the qualified registry-based reporting mechanism, the group practice would be subject to the Measures Applicability

Validation process, which would allow us to determine whether a group practice should have reported on additional measures and/or measures covering additional National Quality Strategy domains. Measures with a 0 percent performance rate would not be counted.

- (iii) <u>Via EHR Direct Product</u>. For the 12-month 2014 PQRS incentive reporting period, for a group practice of 2 or more eligible professionals, report 9 measures covering at least 3 of the National Quality Strategy domains. If a group practice's CEHRT does not contain patient data for at least 9 measures covering at least 3 domains, then the group practice must report the measures for which there is Medicare patient data. A group practice must report on at least 1 measure for which there is Medicare patient data.
- (iv) <u>Via EHR Data Submission Vendor</u>. For the 12-month 2014 PQRS incentive reporting period, for a group practice of 2 or more eligible professionals, report 9 measures covering at least 3 of the National Quality Strategy domains. If a group practice's CEHRT does not contain patient data for at least 9 measures covering at least 3 domains, then the group practice must report the measures for which there is Medicare patient data. A group practice must report on at least 1 measure for which there is Medicare patient data.
- (v) <u>Via a Certified survey vendor, in addition to the GPRO web interface, qualified registry, direct EHR product, or EHR data submission vendor reporting mechanisms</u>. For the 12-month 2014 PQRS incentive reporting period, for a group practice of 25 or more eligible professionals, report all CG CAHPS survey measures via a CMS-certified survey vendor, and report at least 6 measures covering at least 2 of the National Quality Strategy domains using a qualified registry, direct EHR product, EHR data submission vendor, or GPRO web interface.
- (i) <u>Satisfactory participation requirements for the incentive payments for individual</u> <u>eligible professionals</u>. To qualify for the 2014 PQRS incentive using a qualified clinical data

registry, an individual eligible professional, as identified by a unique TIN/NPI combination, must meet the criteria for satisfactory participation as specified under paragraph (i)(3) of this section by reporting on quality measures identified by a qualified clinical data registry during a reporting period specified in paragraph (i)(1) of this section, and using the reporting mechanism specified in paragraph (i)(2) of this section.

- (1) <u>Reporting period</u>. For purposes of this paragraph, the reporting period is the 12–month period from January 1 through December 31.
- (2) <u>Reporting Mechanism</u>. An individual eligible professional who wishes to meet the criteria for satisfactory participation in a qualified clinical data registry must use a qualified clinical data registry to report information on quality measures identified by the qualified clinical data registry.
- (3) <u>Satisfactory participation criteria for individual eligible professionals for the 2014</u>

 <u>PQRS incentive</u>. An individual eligible professional who wishes to qualify for the 2014 PQRS incentive through satisfactory participation in a qualified clinical data registry must report information on quality measures identified by the qualified clinical data registry in the following manner:
- (i) For the 12-month 2014 PQRS incentive reporting period, report at least 9 measures designated for reporting under a qualified clinical data registry covering at least 3 of the National Quality Strategy domains and report each measure for at least 50 percent of the eligible professional's patients. Of the measures reported via a qualified clinical data registry, the eligible professional must report on at least 1 outcome measure.
 - (ii) [Reserved].

(j) Satisfactory reporting requirements for the payment adjustments. In order to satisfy the requirements for the PQRS payment adjustment for a particular program year, an individual eligible professional, as identified by a unique TIN/NPI combination, or a group practice must meet the criteria for satisfactory reporting specified by CMS for such year by reporting on either individual PQRS measures or PQRS measures groups identified by CMS during a reporting period specified in paragraph (j)(1) of this section, using one of the reporting mechanisms specified in paragraph (j)(2) or (4) of this section, and using one of the reporting criteria specified in section (j)(3) or (5) of this section.

- (1) For purposes of this paragraph (j), the reporting period for the payment adjustment, with respect to a payment adjustment year, is the 12–month period from January 1 through December 31 that falls 2 years prior to the year in which the payment adjustment is applied.
- (i) For the 2015 and 2016 PQRS payment adjustments only, an alternative 6-month reporting period, from July 1-December 31 that fall 2 years prior to the year in which the payment adjustment is applied, is also available.
 - (ii) [Reserved]
- (2) <u>Reporting mechanisms for individual eligible professionals</u>. An individual eligible professional participating in the PQRS must report information on PQRS quality measures identified by CMS in one of the following manners:
- (i) <u>Claims</u>. Reporting PQRS quality measures or PQRS measures groups to CMS, by no later than 2 months after the end of the applicable reporting period, on the eligible professional's Medicare Part B claims for covered professional services furnished during the applicable reporting period.

(A) If an eligible professional re-submits a Medicare Part B claim for reprocessing, the eligible professional may not attach a G-code at that time for reporting on individual PQRS measures or measures groups.

- (B) [Reserved]
- (ii) <u>Registry</u>. Reporting PQRS quality measures or PQRS measures groups to a qualified registry in the form and manner and by the deadline specified by the qualified registry selected by the eligible professional. The selected registry must submit information, as required by CMS, for covered professional services furnished by the eligible professional during the applicable reporting period to CMS on the eligible professional's behalf.
- (iii) <u>Direct EHR product</u>. Reporting PQRS quality measures to CMS by extracting clinical data using a secure data submission method, as required by CMS, from a direct EHR product by the deadline specified by CMS for covered professional services furnished by the eligible professional during the applicable reporting period.
- (iv) EHR data submission vendor. Reporting PQRS quality measures to CMS by extracting clinical data using a secure data submission method, as required by CMS, from an EHR data submission vendor product by the deadline specified by CMS for covered professional services furnished by the eligible professional during the applicable reporting period.
- (v) <u>Administrative claims</u>. For 2015, reporting data on PQRS quality measures via administrative claims during the applicable reporting period. Eligible professionals that are administrative claims reporters must meet the following requirement for the payment adjustment:
 - (A) Elect to participate in the PQRS using the administrative claims reporting option.
- (B) Reporting Medicare Part B claims data for CMS to determine whether the eligible professional has performed services applicable to certain individual PQRS quality measures.

(3) <u>Satisfactory reporting criteria for individual eligible professionals for the 2016 PQRS</u> payment adjustment. An individual eligible professional who wishes to meet the criteria for satisfactory reporting for the 2016 PQRS payment adjustment must report information on PQRS quality measures identified by CMS in one of the following manners:

- (i) <u>Via Claims</u>. (A) For the 12-month 2016 PQRS payment adjustment reporting period—
- (1)(i) Report at least 9 measures covering at least 3 National Quality Strategy domains and report each measure for at least 50 percent of the Medicare Part B FFS patients seen during the reporting period to which the measure applies; or if less than 9 measures covering at least 3 NQS domains apply to the eligible professional, report 1—8 measures covering 1—3 National Quality Strategy domains, and report each measure for at least 50 percent of the Medicare Part B FFS patients seen during the reporting period to which the measure applies. For an eligible professional who reports fewer than 9 measures covering at least 3 NQS domains via the claims-based reporting mechanism, the eligible professional would be subject to the Measures Applicability Validation process, which would allow us to determine whether an eligible professional should have reported quality data codes for additional measures and/or covering additional National Quality Strategy domains; or
- (<u>ii</u>) Report at least 3 measures covering at least 1 NQS domain, or, if less than 3 measures covering at least 1 NQS domain apply to the eligible professional, report 1—2 measures covering at least 1 NQS domain; and report each measure for at least 50 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies.
 - (2) Measures with a 0 percent performance rate would not be counted.

(ii) <u>Via Qualified Registry</u>. (A) For the 12-month 2016 PQRS payment adjustment reporting period—

- (1)(i) Report at least 9 measures covering at least 3 of the National Quality Strategy domains; or if less than 9 measures covering at least 3 NQS domains apply to the eligible professional, report 1 to 8 measures covering 1 to 3 National Quality Strategy domains for which there is Medicare patient data, and report each measure for at least 50 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. For an eligible professional who reports fewer than 9 measures covering at least 3 NQS domains via the qualified registry-based reporting mechanism, the eligible professional would be subject to the Measures Applicability Validation process, which would allow us to determine whether an eligible professional should have reported on additional measures and/or measures covering additional National Quality Strategy domains; or
- (ii) Report at least 3 measures covering at least 1 of the NQS domains; or if less than 3 measures covering at least 1 NQS domain apply to the eligible professional, report 1 to 2 measures covering 1 National Quality Strategy domain for which there is Medicare patient data, and report each measure for at least 50 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. For an eligible professional who reports fewer than 3 measures covering 1 NQS domain via the registry-based reporting mechanism, the eligible professional would be subject to the Measures Applicability Validation process, which would allow us to determine whether an eligible professional should have reported on additional measures; or
- (<u>iii</u>) Report at least 1 measures group and report each measures group for at least 20 patients, a majority of which much be Medicare Part B FFS patients.

(2)Measures with a 0 percent performance rate or measures groups containing a measure with a 0 percent performance rate will not be counted.

- (B) For the 6-month 2016 PQRS payment adjustment reporting period—
- (1) Report at least 1 measures group and report each measures group for at least 20 patients, a majority of which much be Medicare Part B FFS patients. Measures groups containing a measure with a 0 percent performance rate will not be counted.
- (iii) <u>Via EHR Direct Product</u>. For the 12-month 2016 PQRS payment adjustment reporting period, report 9 measures covering at least 3 of the National Quality Strategy domains. If an eligible professional's CEHRT does not contain patient data for at least 9 measures covering at least 3 domains, then the eligible professional must report the measures for which there is Medicare patient data. An eligible professional must report on at least 1 measure for which there is Medicare patient data.
- (iv) <u>Via EHR Data Submission Vendor</u>. For the 12-month 2016 PQRS payment adjustment reporting period, report 9 measures covering at least 3 of the National Quality Strategy domains. If an eligible professional's CEHRT does not contain patient data for at least 9 measures covering at least 3 domains, then the eligible professional must report the measures for which there is Medicare patient data. An eligible professional must report on at least 1 measure for which there is Medicare patient data.
- (4) <u>Reporting mechanisms for group practices</u>. With the exception of a group practice who wishes to participate in the PQRS using the certified survey vendor mechanism, a group practice participating in the PQRS must report information on PQRS quality measures identified by CMS in one of the following reporting mechanisms:

(i) Web interface. For the 2015 payment adjustment and subsequent payment adjustments, reporting PQRS quality measures to CMS using a CMS web interface in the form and manner and by the deadline specified by CMS.

- (ii) <u>Registry</u>. For the 2015 subsequent adjustment and subsequent payment adjustments, reporting on PQRS quality measures to a qualified registry in the form and manner and by the deadline specified by the qualified registry selected by the eligible professional. The selected registry will submit information, as required by CMS, for covered professional services furnished by the eligible professional during the applicable reporting period to CMS on the eligible professional's behalf.
- (iii) <u>Direct EHR product</u>. For the 2016 subsequent adjustment and subsequent payment adjustments, reporting PQRS quality measures to CMS by extracting clinical data using a secure data submission method, as required by CMS, from a direct EHR product by the deadline specified by CMS for covered professional services furnished by the eligible professional during the applicable reporting period.
- (iv) EHR data submission vendor. For the 2016 subsequent adjustment and subsequent payment adjustments, reporting PQRS quality measures to CMS by extracting clinical data using a secure data submission method, as required by CMS, from an EHR data submission vendor product by the deadline specified by CMS for covered professional services furnished by the group practice during the applicable reporting period.
- (v) <u>Administrative claims</u>. For 2015, reporting data on PQRS quality measures via administrative claims during the applicable reporting period. Group practices that are administrative claims reporters must meet the following requirement for the payment adjustment:
 - (A) Elect to participate in the PQRS using the administrative claims reporting option.

(B) Reporting Medicare Part B claims data for CMS to determine whether the group practice has performed services applicable to certain individual PQRS quality measures.

- (vi) <u>Certified Survey Vendors</u>. For 2016 and subsequent years, reporting CAHPS survey measures to CMS using a vendor that is certified by CMS for a particular program year to transmit survey measures data to CMS. Group practices that elect this reporting mechanism must select an additional group practice reporting mechanism in order to meet the criteria for satisfactory reporting for the payment adjustment.
- (5) <u>Satisfactory reporting criteria for group practices for the 2016 PQRS payment</u> adjustment. A group practice who wishes to meet the criteria for satisfactory reporting for the 2016 PQRS payment adjustment must report information on PQRS quality measures identified by CMS in one of the following manners:
- (i) <u>Via the GPRO web interface</u>. (A) For the 12-month 2016 PQRS payment adjustment reporting period, for a group practice of 25 to 99 eligible professionals, report on all measures included in the web interface and populate data fields for the first 218 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 218, then report on 100 percent of assigned beneficiaries.
- (B) For the 12-month 2016 PQRS payment adjustment reporting period, for a group practice of 100 or more eligible professionals, report on all measures included in the web interface and populate data fields for the first 411 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 411, then

report on 100 percent of assigned beneficiaries. In addition, the group practice must also report all CG CAHPS survey measures via certified survey vendor.

- (ii) <u>Via Qualified Registry</u>. (A) For the 12-month 2016 PQRS payment adjustment reporting period, for a group practice of 2 or more eligible professionals--
- (1) Report at least 9 measures, covering at least 3 of the National Quality Strategy domains and report each measure for at least 50 percent of the group practices's Medicare Part B FFS patients seen during the reporting period to which the measure applies; or If less than 9 measures covering at least 3 NQS domains apply to the eligible professional, then the group practices must report 1-8 measures for which there is Medicare patient data and report each measure for at least 50 percent of the group practices's Medicare Part B FFS patients seen during the reporting period to which the measure applies. For a group practice who reports fewer than 9 measures covering at least 3 NQS domains via the registry-based reporting mechanism, the group practice would be subject to the Measures Applicability Validation process, which would allow us to determine whether an group practice should have reported on additional measures. Measures with a 0 percent performance rate would not be counted; or
- (2) Report at least 3 measures, covering at least 1 of the National Quality Strategy domains and report each measure for at least 50 percent of the group practice's Medicare Part B FFS patients seen during the reporting period to which the measure applies; or if less than 3 measures covering at least 1 NQS domain apply to the group practice, then the group practice must report 1-2 measures for which there is Medicare patient data and report each measure for at least 50 percent of the group practice's Medicare Part B FFS patients seen during the reporting period to which the measure applies. For a group practice who reports fewer than 3 measures covering at least 1 NQS domain via the registry-based reporting mechanism, the group practice

would be subject to the Measures Applicability Validation process, which would allow us to determine whether an group practice should have reported on additional measures. Measures with a 0 percent performance rate would not be counted.

- (iii) <u>Via EHR Direct Product</u>. For a group practice of 2 or more eligible professionals, for the 12-month 2016 PQRS payment adjustment reporting period, report 9 measures covering at least 3 of the National Quality Strategy domains. If a group practice's CEHRT does not contain patient data for at least 9 measures covering at least 3 domains, then the group practice must report the measures for which there is Medicare patient data. A group practice must report on at least 1 measure for which there is Medicare patient data.
- (iv) <u>Via EHR Data Submission Vendor</u>. For a group practice of 2 or more eligible professionals, for the 12-month 2016 PQRS payment adjustment reporting period, report 9 measures covering at least 3 of the National Quality Strategy domains. If a group practice's CEHRT does not contain patient data for at least 9 measures covering at least 3 domains, then the group practice must report the measures for which there is Medicare patient data. A group practice must report on at least 1 measure for which there is Medicare patient data.
- (v) Via a Certified survey vendor, in addition to the GPRO web interface, qualified registry, direct EHR product, or EHR data submission vendor reporting mechanisms. For a group practice of 25 or more eligible professionals, for the 12-month 2016 PQRS payment adjustment reporting period, report all CG CAHPS survey measures via a CMS-certified survey vendor and report at least 6 measures covering at least 2 of the National Quality Strategy domains using a qualified registry, direct EHR product, EHR data submission vendor, or GPRO web interface.

(k) Satisfactory participation requirements for the payment adjustments for individual eligible professionals. In order to satisfy the requirements for the PQRS payment adjustment for a particular program year through participation in a qualified clinical data registry, an individual eligible professional, as identified by a unique TIN/NPI combination, must meet the criteria for satisfactory participation as specified in paragraph (k)(3) for such year, by reporting on quality measures identified by a qualified clinical data registry during a reporting period specified in paragraph (k)(1) of this section, using the reporting mechanism specified in paragraph (k)(2) of this section.

- (1) Reporting period. For purposes of this paragraph, the reporting period is—
- (i) The 12-month period from January 1 through December 31 that falls 2 years prior to the year in which the payment adjustment is applied.
 - (ii) [Reserved.]
- (2) <u>Reporting Mechanism</u>. An individual eligible professional who wishes to meet the criteria for satisfactory participation in a qualified clinical data registry must use the qualified clinical data registry to report information on quality measures identified by the qualified clinical data registry.
- (3) Satisfactory participation criteria for individual eligible professionals for the 2016 PQRS payment adjustment. An individual eligible professional who wishes to meet the criteria for satisfactory participation in a qualified clinical data registry for the 2016 PQRS payment adjustment must report information on quality measures identified by the qualified clinical data registry in one of the following manners:
 - (i) For the 12-month 2016 PQRS payment adjustment reporting period—

(A) Report at least 9 measures available for reporting under a qualified clinical data registry covering at least 3 of the National Quality Strategy domains and report each measure for at least 50 percent of the eligible professional's patients; or

- (B) Report at least 3 measures available for reporting under a qualified clinical data registry covering at least 1 of the National Quality Strategy domains and report each measure for at least 50 percent of the eligible professional's patients
- (l) <u>Requirements for group practices</u>. Under the PQRS, a group practice must meet all of the following requirements:
- (1) Meet the participation requirements specified by CMS for the PQRS group practice reporting option.
 - (2) Report measures in the form and manner specified by CMS.
 - (3) Meet other requirements for satisfactory reporting specified by CMS.
 - (4) Meet other requirements for satisfactory reporting specified by CMS.
 - (5) Meet participation requirements.
- (i) If an eligible professional, as identified by an individual NPI, has reassigned his or her Medicare billing rights to a group practice (as identified by the TIN) selected to participate in the PQRS group practice reporting option for a program year, then for that program year the eligible professional must participate in the PQRS via the group practice reporting option.
- (ii) If, for the program year, the eligible professional participates in the PQRS as part of a group practice (as identified by the TIN) that is not selected to participate in the PQRS group practice reporting option for that program year, then the eligible professional may individually participate and qualify for a PQRS incentive by meeting the requirements specified in paragraph (g) of this section under that TIN.

(m) <u>Informal review</u>. Eligible professionals or group practices may seek an informal review of the determination that an eligible professional or group practices did not satisfactorily submit data on quality measures under the PQRS, or, for individual eligible professionals, in lieu of satisfactory reporting, did not satisfactorily participate in a qualified clinical data registry.

- (1) To request an informal review, an eligible professional or group practices must submit a request to CMS within 90 days of the release of the feedback reports. The request must be submitted in writing and summarize the concern(s) and reasons for requesting an informal review and may also include information to assist in the review.
- (2) CMS will provide a written response within 90 days of the receipt of the original request.
 - (i) All decisions based on the informal review will be final.
 - (ii) There will be no further review or appeal.
- (n) <u>Limitations on review</u>. Except as specified in paragraph (i) of this section, there is no administrative or judicial review under section 1869 or 1879 of the Act, or otherwise of—
- (1) The determination of measures applicable to services furnished by eligible professionals under the PQRS;
 - (2) The determination of satisfactory reporting; and
- (3) The determination of any Physician Quality Reporting System incentive payment and the PQRS payment adjustment.
- (o) <u>Public reporting of an eligible professional's or group practice's PQRS data</u>. For each program year, CMS will post on a public Web site, in an easily understandable format, a list of the names of eligible professionals (or in the case of reporting under paragraph (g) of this section, group practices) who satisfactorily submitted PQRS quality measures.

32. Section 414.511 is added to subpart G to read as follows:

§414.511 Adjustments to the Clinical Laboratory Fee Schedule based on Technological Changes.

- (a) CMS may make adjustments to the fee schedules as CMS determines are justified by technological changes.
- (b) Technological changes are changes to the tools, machines, supplies, labor, instruments, skills, techniques, and devices by which laboratory tests are produced and used.
- (c) CMS will propose and finalize any adjustments to the fee schedules as CMS determines are justified by technological changes in the **Federal Register**.
 - 33. Section 414.610 is amended by—
 - A. Revising paragraphs (c)(1)(ii) and (c)(5)(ii).
 - B. Adding paragraph (c)(8).
 - C. Revising paragraph (h).

The revisions and addition read as follows:

§414.610 Basis of payment.

- * * * * * *

 (c)* * *

 (1)* * *
- (ii) For services furnished during the period July 1, 2008 through December 31, 2013, ambulance services originating in:
- (A) Urban areas (both base rate and mileage) are paid based on a rate that is 2 percent higher than otherwise is applicable under this section.
- (B) Rural areas (both base rate and mileage) are paid based on a rate that is 3 percent higher than otherwise is applicable under this section.

- (5) * * *
- (ii) For services furnished during the period July 1, 2004 through December 31, 2013, the payment amount for the ground ambulance base rate is increased by 22.6 percent where the point of pickup is in a rural area determined to be in the lowest 25 percent of rural population arrayed by population density. The amount of this increase is based on CMS's estimate of the ratio of the average cost per trip for the rural areas in the lowest quartile of population compared to the average cost per trip for the rural areas in the highest quartile of population. In making this estimate, CMS may use data provided by the GAO.

* * * * *

(8) For ambulance services furnished on or after October 1, 2013 consisting of non-emergency basic life support (BLS) services involving transport of an individual with end-stage renal disease for renal dialysis services (as described in section 1881(b)(14)(B)) furnished other than on an emergency basis by a provider of services or a renal dialysis facility, the fee schedule amount otherwise applicable (both base rate and mileage) is reduced by 10 percent.

- (h) <u>Treatment of certain areas for payment for air ambulance services</u>. Any area that was designated as a rural area for purposes of making payments under the ambulance fee schedule for air ambulance services furnished on December 31, 2006, must be treated as a rural area for purposes of making payments under the ambulance fee schedule for air ambulance services furnished during the period July 1, 2008 through June 30, 2013.
- 34. Section 414.1210 is amended by revising paragraphs (a) and (c) to read as follows: **§414.1210 Application of the value-based payment modifier.**
 - (a) The value-based payment modifier is applicable:
- (1) For the CY 2015 payment adjustment period, to physicians in groups with 100 or more eligible professionals based on the performance period described at § 414.1215(a).

(2) For the CY 2016 payment adjustment period, to physicians in groups with 10 or more eligible professionals based on the performance period described at § 414.1215(b).

* * * * *

- (c) Group size determination. The list of groups of physicians subject to the value-based payment modifier for the CY 2015 payment adjustment period is based on a query of PECOS on October 15, 2013. For each subsequent calendar year payment adjustment period, the list of groups of physicians subject to the value-based payment modifier is based on a query of PECOS that occurs within 10 days of the close of the Physician Quality Reporting System group registration process during the applicable performance period described at § 414.1215. Groups of physicians are removed from the PECOS-generated list if, based on a claims analysis, the group of physicians did not have the required number of eligible professionals, as defined in §414.1210(a), that submitted claims during the performance period for the applicable calendar year payment adjustment period.
- 35. Section 414.1215 is amended by adding paragraph (c) to read as follows: § 414.1215 Performance and payment adjustment periods for the value-based payment modifier.

* * * * *

- (c) The performance period is calendar year 2015 for value-based payment modifier adjustments made in the calendar year 2017 payment adjustment period.
 - 36. Section 414.1220 is revised to read as follows:

§ 414.1220 Reporting mechanisms for the value-based payment modifier.

Groups of physicians subject to the value-based payment modifier (or individual eligible professionals within such groups) may submit data on quality measures as specified under the

Physician Quality Reporting System using the reporting mechanisms for which they are eligible.

37. Section 414.1225 is revised to read as follows:

§ 414.1225 Alignment of Physician Quality Reporting System quality measures and quality measures for the value-based payment modifier.

All of the quality measures for which groups of physicians or individual eligible professionals are eligible to report under the Physician Quality Reporting System in a given calendar year are used to calculate the value-based payment modifier for the applicable payment adjustment period, as defined in §414.1215, to the extent a group of physicians or individual eligible professionals within such group submits data on such measures.

38. Section 414.1235 is revised to read as follows:

§ 414.1235 Cost measures.

- (a) <u>Included measures</u>. Beginning with the CY 2016 payment adjustment period, costs for groups of physicians subject to the value-based payment modifier are assessed based on a cost composite comprised of the following 6 cost measures (only the measures identified in paragraphs (a)(1) through (5) of this section are included for the value-based payment modifier for the CY 2015 payment adjustment period):
 - (1) Total per capita costs for all attributed beneficiaries.
 - (2) Total per capita costs for all attributed beneficiaries with diabetes.
 - (3) Total per capita costs for all attributed beneficiaries with coronary artery disease.
- (4) Total per capita costs for all attributed beneficiaries with chronic obstructive pulmonary disease.
 - (5) Total per capita costs for all attributed beneficiaries with heart failure.
 - (6) Medicare Spending per Beneficiary associated with an acute inpatient

hospitalization.

(b) <u>Included payments</u>. Cost measures enumerated in paragraph (a) of this section include all fee-for-service payments made under Medicare Part A and Part B.

- (c) <u>Cost measure adjustments</u>. (1) Payments under Medicare Part A and Part B will be adjusted using CMS' payment standardization methodology to ensure fair comparisons across geographic areas.
- (2) The CMS-HCC model (and adjustments for ESRD status) is used to adjust standardized payments for the measures listed at paragraphs (a)(1) through (5) of this section.
- (3) The beneficiary's age and severity of illness are used to adjust the Medicare Spending per Beneficiary measure as specified in paragraph (a)(6) of this section.
 - 39. Section 414.1240 is revised to read as follows:

§ 414.1240 Attribution for quality of care and cost measures.

- (a) Beneficiaries are attributed to groups of physicians subject to the value-based payment modifier using a method generally consistent with the method of assignment of beneficiaries under §425.402 of this chapter, for measures other than the Medicare Spending per Beneficiary measure.
- (b) For the Medicare Spending per Beneficiary (MSPB) measure, an MSPB episode is attributed to the group of physicians subject to the value-based payment modifier whose eligible professionals submitted the plurality of claims (as measured by allowable charges) under the group's TIN for Medicare Part B services, rendered during an inpatient hospitalization that is an index admission for the MSPB measure during the applicable performance period described at § 414.1215.
 - 40. Section 414.1255 is revised to read as follows:

§ 414.1255 Benchmarks for cost measures.

(a) For the CY 2015 payment adjustment period, the benchmark for each cost measure is the national mean of the performance rates calculated among all groups of physicians for which beneficiaries are attributed to the group of physicians that are subject to the value-based payment modifier. In calculating the national benchmark, groups of physicians' performance rates are weighted by the number of beneficiaries used to calculate the group of physician's performance rate.

- (b) Beginning with the CY 2016 payment adjustment period, the cost measures of a group of physicians subject to the value-based payment modifier are adjusted to account for the group's specialty mix, by computing the weighted average of the national specialty-specific expected costs. Each national specialty-specific expected cost is weighted by the proportion of each specialty in the group, the number of eligible professionals of each specialty in the group, and the number of beneficiaries attributed to the group.
- (c) The national specialty-specific expected costs referenced in paragraph (b) of this section are derived by calculating, for each specialty, the average cost of beneficiaries attributed to groups of physicians that include that specialty.
- 41. Section 414.1260 is amended by revising paragraph (b)(1)(i) to read as follows: § 414.1260 Composite scores.

- (b) * * *
- (1) * * *
- (i) Total per capita costs for all attributed beneficiaries: Total per capita costs measure and Medicare Spending per Beneficiary measure; and

* * * * *

42. Section 414.1270 is revised to read as follows:

§ 414.1270 Determination and calculation of Value-Based Payment Modifier adjustments.

- (a) For the CY 2015 payment adjustment period:
- (1) <u>Downward payment adjustments</u>. A downward payment adjustment will be applied to a group of physicians subject to the value-based payment modifier if--
- (i) Such group neither self-nominates for the PQRS GPRO and reports at least one measure, nor elects the PQRS administrative claims option for CY 2013 as defined in §414.90(h).
 - (A) Such adjustment will be -1.0 percent.
 - (B) [Reserved].
- (ii) Such group elects that its value-based payment modifier be calculated using a quality-tiering approach, and is determined to have poor performance (low quality and high costs; low quality and average costs; or average quality and high costs).
 - (A) Such adjustment will not exceed -1.0 percent as specified in §414.1275(c)(1).
 - (B) [Reserved].
- (2) No payment adjustments. There will be no value-based payment modifier adjustment applied to a group of physicians subject to the value-based payment modifier if such group either:
 - (i) Self-nominates for the PQRS GPRO and reports at least one measure; or
 - (ii) Elects the PQRS administrative claims option for CY 2013 as defined in §414.90(h).
- (3) <u>Upward payment adjustments</u>. If a group of physicians subject to the value-based payment modifier elects that the value-based payment modifier be calculated using a quality-

tiering approach, upward payment adjustments are determined based on the projected aggregate amount of downward payment adjustments determined under paragraph (a)(1) of this section and applied as specified in §414.1275(c)(1).

- (b) For the CY 2016 payment adjustment period:
- (1) A downward payment adjustment of -2.0 percent will be applied to a group of physicians subject to the value-based payment modifier if, during the applicable performance period as defined in §414.1215, the following apply:
- (i) Such group does not self-nominate for the PQRS GPRO and meet the criteria as a group to avoid the PQRS payment adjustment for CY 2016 as specified by CMS; and
- (ii) Fifty percent of the eligible professionals in such group do not meet the criteria as individuals to avoid the PQRS payment adjustment for CY 2016 as specified by CMS.
- (2) For a group of physicians comprised of 100 or more eligible professionals that is not included in paragraph (b)(1) of this section, the value-based payment modifier adjustment will be equal to the amount determined under §414.1275(c)(2).
- (3) For a group of physicians comprised of between 10 and 99 eligible professionals that is not included in paragraph (b)(1) of this section, the value-based payment modifier adjustment will be equal to the amount determined under §414.1275(c)(2), except that such adjustment will be 0.0 percent if the group of physicians is determined to be low quality/high cost, low quality/average cost, or average quality/high cost.
- (4) If all of the eligible professionals in a group of physicians subject to the value-based payment modifier participate as individuals in the PQRS using a qualified clinical data registry or any other reporting mechanism available to them, and CMS is unable to receive quality performance data for those eligible professionals under that reporting mechanism, the quality

composite score for such group will be classified as "average" under §414.1275(b)(1).

(5) A group of physicians subject to the value-based payment modifier will receive a cost composite score that is classified as "average" under §414.1275(b)(2) if such group does not have at least one cost measure with at least 20 cases.

43. Section 414.1275 is amended by revising paragraphs (a) and (c) and (d) introductory text to read as follows:

§ 414.1275 Value-based payment modifier quality-tiering scoring methodology.

(a) The value-based payment modifier amount for a group of physicians subject to the value-based payment modifier is based upon a comparison of the composite of quality of care measures and a composite of cost measures.

* * * * *

(c)(1) The following value-based payment modifier percentages apply to the CY 2015 payment adjustment period:

CY 2015 Value-Based Payment Modifier Amounts for the Quality-Tiering Approach

Quality/cost	Low cost	Average cost	High cost
High quality	+2.0x*	+1.0x*	+0.0%
Average quality	+1.0x*	+0.0%	-0.5%
Low quality	+0.0%	-0.5%	-1.0%

^{*} Groups of physicians eligible for an additional +1.0x if (1) reporting Physician Quality Reporting System quality measures through the GPRO web-interface or CMS-qualified registry, and (2) average beneficiary risk score is in the top 25 percent of all beneficiary risk scores.

(2) The following value-based payment modifier percentages apply to the CY 2016 payment adjustment period:

CY 2016 Value-Based Payment Modifier Amounts for the Quality-Tiering Approach

Quality/cost	Low cost	Average cost	High cost
High quality	+2.0x*	+1.0x*	+0.0%
Average quality	+1.0x*	+0.0%	-1.0%
Low quality	+0.0%	-1.0%	-2.0%

* Groups of physicians eligible for an additional +1.0x if reporting Physician Quality Reporting System quality measures and average beneficiary risk score is in the top 25 percent of all beneficiary risk scores.

(d) Groups of physicians subject to the value-based payment modifier that have an attributed beneficiary population with an average risk score in the top 25 percent of the risk scores of beneficiaries nationwide and for the CY 2015 payment adjustment period elect the quality-tiering approach or for the CY 2016 payment adjustment period are subject to the quality-tiering approach, receive a greater upward payment adjustment as follows:

* * * * *

PART 423--VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

44. The authority citation for part 423 continues to read as follows:

Authority: Sections 1102, 1106, 1860D-1 through 1860D-42, and 1871 of the Social Security Act (42 U.S.C. 1302, 1306, 1395w-101 through 1395w-152, and 1395hh).

- 45. Section 423.160 is amended by—
- A. Revising paragraphs (b)(1)(i) through (iii).
- B. Adding paragraphs (b)(1)(iv), (b)(5)(i) through (iii), and (c)(1)(vi).

The revisions and additions read as follows:

§423.160 Standards for electronic prescribing.

- * * * * * * (b) * * *
 - (1)**
- (i) Prior to April 1, 2009, the standards specified in paragraphs (b)(2)(i), (b)(3) and (4), (b)(5)(i), and (b)(6).
 - (ii) On or after April 1, 2009, to February 7, 2014, the standards specified in paragraphs

- (b)(2)(ii), (b)(3)and (4), (b)(5)(i)and (b)(6).
- (iii) From February 8, 2014, until February 28, 2015, the standards specified in paragraphs (b)(2)(ii), (b)(3) and (4), (b)(5)(ii), and (b)(6).
- (iv) From March 1, 2015, the standards specified in paragraphs (b)(2)(ii), (b)(3) and (b)(4), (b)(5)(iii), and (b)(6).
- * * * * *
 - (5)* * *
- (i) <u>Formulary and benefits</u>. Before The National Council for Prescription Drug Programs Formulary and Benefits Standard, Implementation Guide, Version 1, Release 0 (Version 1.0), October 2005 (incorporated by reference in paragraph (c)(1)(ii) of this section) for transmitting formulary and benefits information between prescribers and Medicare Part D sponsors.
- (ii) Formulary and benefits. On The National Council for Prescription Drug Programs

 Formulary and Benefits Standard, Implementation Guide, Version 1, Release 0 (Version 1.0),

 October 2005 (incorporated by reference in paragraph (c)(1)(ii) of this section), or The National

 Council for Prescription Drug Programs Formulary and Benefits Standard, Implementation

 Guide, Version 3, Release 0 (Version 3.0), April 2012 (incorporated by reference in paragraph

 (c)(1)(vi) of this section) for transmitting formulary and benefits information between prescribers and Medicare Part D sponsors.
- (iii) Formulary and benefits. The National Council for Prescription Drug Programs Formulary and Benefits Standard, Implementation Guide, Version 3, Release 0 (Version 3.0), April 2012 (incorporation by reference in paragraph (c)(1)(vi) of this section) for transmitting formulary and benefits information between prescribers and Medicare Part D sponsors.

- (c) * * *
- (1) * *

(vi) The National Council for Prescription Drug Programs Formulary and Benefits Standard, Implementation Guide, Version 3, Release 0 (Version 3.0), published April 2012.

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PART 425—MEDICARE SHARED SAVINGS PROGRAM

46. The authority citation for part 425 continues to read as follows:

Authority: Secs. 1102, 1106, 1871, and 1899 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

47. Section 425.308 is amended by revising paragraph (e) to read as follows:

§425.308 Public reporting and transparency.

* * * * *

- (e) <u>Results of claims based measures</u>. Quality measures reported using a CMS web interface and patient experience of care survey measures will be reported on Physician Compare in the same way as for the group practices that report under the Physician Quality Reporting System.
 - 48. Section 425.502 is amended by revising paragraph (b)(2) to read as follows:

§425.502 Calculating the ACO quality performance score.

- (b) * * *
- (2)(i) CMS will define the quality benchmarks using fee-for-service Medicare data.
- (ii) CMS will set benchmarks using flat percentages when the 60th percentile is equal to or greater than 80.00 percent.

(iii) CMS reserves the right to use flat percentages for other measures when CMS determines that fee-for-service Medicare data are unavailable, inadequate, or unreliable to set the quality benchmarks.

* * * * *

- 49. Section 425.504 is amended by:
- A. Revising the section heading.
- B. Revising paragraphs (a)(1), (b) heading, and (b)(1).
- C. Adding paragraphs (c) and (d).

The revisions and additions read as follows:

§425.504 Incorporating reporting requirements related to the Physician Quality Reporting System Incentive and Payment Adjustment.

- (a) * * *
- (1) ACOs, on behalf of their ACO provider/suppliers who are eligible professionals, must submit the measures determined under §425.500 using a CMS web interface, to qualify on behalf of their eligible professionals for the Physician Quality Reporting System incentive under the Shared Savings Program.

* * * * *

(b) Physician Quality Reporting System payment adjustment for 2015. (1) ACOs, on behalf of their ACO providers/suppliers who are eligible professionals, must submit one of the ACO GPRO measures determined under §425.500 using a CMS web interface, to satisfactorily report on behalf of their eligible professionals for purposes of the 2015 Physician Quality Reporting System payment adjustment under the Shared Savings Program.

(c) <u>Physician Quality Reporting System payment adjustment for 2016 and subsequent years</u>. (1) ACOs, on behalf of their ACO providers/suppliers who are eligible professionals, must submit all of the ACO GPRO measures determined under §425.500 using a CMS web interface, to satisfactorily report on behalf of their eligible professionals for purposes of the Physician Quality Reporting System payment adjustment under the Shared Savings Program for 2016 and subsequent years.

- (2) ACO providers/suppliers that are eligible professionals within an ACO may only participate under their ACO participant TIN as a group practice under the Physician Quality Reporting System Group Practice Reporting Option of the Shared Savings Program for purposes of the Physician Quality Reporting System payment adjustment under the Shared Savings Program for 2016 and subsequent years.
- (3) If an ACO, on behalf of its ACO providers/suppliers who are eligible professionals, does not satisfactorily report for purposes of the Physician Quality Reporting System payment adjustment for 2016 and subsequent years, each ACO provider/supplier who is an eligible professional, will receive a payment adjustment, as described in § 414.90(e) of this chapter.
- (4) For eligible professionals subject to the Physician Quality Reporting System payment adjustment under the Medicare Shared Savings Program for 2016 and subsequent years, the Medicare Part B Physician Fee Schedule amount for covered professional services furnished during the program year is equal to the applicable percent of the Medicare Part B Physician Fee Schedule amount that would otherwise apply to such services under section 1848 of the Act, as described in § 414.90(e) of this chapter.
- (d) The reporting period for a year is the calendar year from January 1 through December 31 that occurs 2 years prior to the program year in which the payment adjustment is applied.

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(Catalog of Federal Domestic Assistance Program No. 93.773, MedicareHospital Insurance;
and Program No. 93.774, MedicareSupplementary Medical Insurance Program)

Dated: November 14, 2013.

Marilyn Tavenner,

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Administrator,

Centers for Medicare & Medicaid Services.

Approved: November 21, 2013.

Kathleen Sebelius,

Secretary,

Department of Health and Human Services.

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